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IN THE

Supreme Court of the United States

OCTOBER TERM 1974

No. 74-1443

OIL, CHEMICAL AND ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO,

and

HEALTH RESEARCH GROUP,

Petitioners,

v.

JOHN T. DUNLOP, Secretary, United States Department of Labor

and

JOHN H. STENDER, Assistant Secretary, Occupational Safety and Health Administration, United States Department of Labor

Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

The Oil, Chemical and Atomic Workers International Union, AFL-CIO, and the Health Research Group hereby respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

OPINION BELOW

The opinion of the United States Court of Appeals for the Third Circuit (Appendix A, *infra*, pp. 1a-13a) is reported at 506 F.2d 385. That opinion reviewed the validity of the issuance by the Secretary of Labor (the "Secretary") of occupational health standards regulating fourteen cancer-causing chemicals. The statement of reasons applicable to all fourteen standards and a representative carcinogen standard issued by the Secretary, 29 C.F.R. §1910.93*c-p*, 39 *Fed. Reg.* 3756 (January 29, 1974), are set out in Appendix B, *infra*, pp. 14a-42a.

JURISDICTION

The judgment of the Court of Appeals was entered on December 17, 1974. (Appendix D, *infra*, p. 45a) The time for filing a petition for writ of certiorari was extended until May 16, 1975 by an order entered on March 6, 1975. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1). Original jurisdiction was invoked in the Court of Appeals under 29 U.S.C. §655(f).

QUESTION PRESENTED

Did the Court of Appeals err in testing the validity of the Secretary's omission of two vital protections from occupational health standards involving fourteen cancer-causing chemicals by asking only whether the Secretary's decision was a reasonable judgment rather than by measuring the decision against the statutory provisions which mandate these vital protections?

STATUTE INVOLVED

Sections 6(b)(5) and 6(b)(7) of the Occupational Safety and Health Act of 1970, 84 Stat. 1594, 1595-1596, 29

U.S.C. §§655(b)(5), 655(b)(7), are set out in Appendix C, *infra*, pp. 43a-44a.

STATEMENT OF THE CASE

Convinced that the human toll from workplace hazards must be effectively controlled, Congress enacted the Occupational Safety and Health Act, 29 U.S.C. §§651 *et seq.* (1970). Section 6(b)(5) of the Act specifically mandated the Secretary to set health and safety standards which ". . . most adequately assure that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure . . . for the period of his working life . . . ." 29 U.S.C. §655(b)(5).[1] To guarantee this protection, Congress concluded that there were certain safeguards which were essential to worker health and safety. One of these protections was the requirement of a specific limit on the level of the toxic material in the work environment, generally referred to as a "performance standard", *Id.* Such a standard enables the Secretary to objectively measure an employer's performance in eliminating the workplace hazard. In addition, Congress required that the standards include a system to detect and measure worker exposure to the hazard so that regular checks would be made of the workplace to measure performance against the promises made ("monitoring") 29 U.S.C. §655(b)(7). This petition seeks review

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[1] The Secretary delegated his functions under the Act to the Assistant Secretary of Labor for Occupational Safety and Health, Secretary's Order #12-71. Both of these officials were respondents in the Court of Appeals and are respondents in this Court.

of (a) the failure of the Secretary to include in the standards regulating fourteen cancer-producing chemicals ("carcinogens") any performance standard whatsoever and his indefinite deferral of any monitoring requirement, and (b) the failure of the Court of Appeals to require the Secretary to amend the standards by providing for these two elements.

A. Administrative Proceedings

The governmental inquiry into the deaths and serious health hazards confronting workers exposed to these fourteen carcinogens began in May 1972 when the Secretary requested the National Institute for Occupational Safety and Health ("NIOSH")[2] to investigate the cancer hazard. NIOSH transmitted fact sheets on these carcinogens to the Secretary in July 1972 and its investigation culminated in a NIOSH request for whatever additional information the public might have. 37 *Fed. Reg.* 13285 (July 6, 1972). Since continued human exposure to these chemicals presented a grave danger, and since the Secretary took no action to regulate them, the Oil, Chemical and Atomic Workers Union ("OCAW") and the Health Research Group, requested the Secretary to issue an emergency temporary standard under section 6(c) of the Act, 29 U.S.C. §655(c). Their petition documented the cancer hazard and proposed a standard which included a performance standard and monitoring among other important protections.[3] Inspite of the urgency of the matter, no standard was promulgated until after the

[2]NIOSH is organized within the Department of Health, Education and Welfare, 29 U.S.C. §671.

[3]The Secretary noticed receipt of the petition and published the text of the standard suggested by the petitioners for public comment, 38 *Fed. Reg.* 4037, 4038-4039 (February 9, 1973).

petitioners filed a mandamus action to compel the Secretary to act on their request for an emergency temporary standard.[4] On May 3, 1973, the Secretary finally issued an emergency standard to deal ". . . with the exposure of employees to certain listed substances that are known to cause cancer." 38 *Fed. Reg.* 10929. Specifically, the Secretary found that: ". . . (1) the 14 carcinogens listed in the emergency temporary standard are toxic and physically harmful; (2) that exposure to any of the 14 substances poses a grave danger to employees; (3) that employees are presently being exposed to the substances; and (4) that the emergency temporary standard set forth below is necessary to protect employees from such exposure." *Id.*

Although the emergency standard required employers using these chemicals to institute certain work practices, it did not place a definite limit on worker exposure to the carcinogens by setting a performance standard. In omitting any limit on worker exposure above fixed levels, the Secretary violated the statutory mandate that ". . . [w]henever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired." 29 U.S.C. §655(b)(5). Moreover, the Secretary did not even require employers to measure worker exposure to these carcinogens, ignoring completely section 6(b)(7) which directs the inclusion of ". . . monitoring or measuring employee exposure . . . as may be necessary for the protection of employees . . ." in these standards. 29 U.S.C. §655(b)(7). Instead, the Secretary merely required employers to report ". . . the type of

[4] *Oil, Chemical & Atomic Workers Int'l Union v. Brennan,* Civil Action No. 730-73 (D.D.C., filed April 17, 1973).

monitoring system [if any] that has been instituted . . ." 38 *Fed. Reg.* 10930 (May 3, 1973), a tactic he also employed with regard to the medical surveillance requirement.[5] In fact, his statutorily required statement of reasons[6] never mentioned any of the mandated protections contained in the Act, let alone explained their omission from the emergency standard.

Petitions for review were filed in the Third Circuit by industry representatives, who challenged the inclusion of two chemicals — EI and DCB — on the list of carcinogens,[7] and by petitioners here, who challenged the adequacy of the protection afforded by the standard in the face of the Secretary's finding that the chemicals posed a grave danger to worker health. Although petitioners urged consideration of the Secretary's failure to follow the statutory mandates of sections 6(b)(5) and 6(b)(7), the Court of Appeals addressed itself exclusively to the industry claim that two of the chemicals were improperly found to be carcinogens, *Dry Color Mfrs. Ass'n v. Dep't of Labor*, 486 F.2d 98 (3d Cir. 1973). The Court set aside those findings because of an inadequate statement of reasons, but declined to address the issues of monitoring, medical surveillance, and a performance standard argued by petitioners. *Id.* at 108.

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[5] Section 6(b)(7) of the Act, 29 U.S.C. §655(b)(7), requires the inclusion of ". . . medical examinations and other tests . . . to most effectively determine whether the health of such [exposed] employees is adversely affected . . . ."

[6] Section 6(e), 29 U.S.C. §655(e).

[7] EI is the acronym for ethyleneimine and DCB the acronym for 3,3'-dichlorobenzidene.

The Act requires the Secretary to replace an emergency temporary standard with a permanent standard within six months. 29 U.S.C. §655(c)(3). In order to obtain expert advice on this new standard, the Secretary convened an advisory committee under section 6(b)(1), 29 U.S.C. § 655(b)(1).[8] But the advisory committee refused to ratify the inadequacies of the emergency standard with the Secretary's deviations from the requirements of the Act. Instead, it recommended a performance standard of "no measurable exposure or contact" to the cancer-producing chemicals. 38 *Fed. Reg.* 24377 (September 7, 1973). The committee also stressed the need for monitoring to detect the presence of these carcinogens in the workplace, and advised the Secretary to include sufficient medical surveillance to determine the adverse effects of continued human exposure to each of these carcinogens. *Id.*

The permanent standard, which was not promulgated until January 29, 1974, almost three months after the statutory deadline, was premised on the conclusion that ". . . a safe level of human exposure to any of the 14 carcinogens cannot be established by the application of present knowledge . . . ." (App. B, p. 20a). However, the Secretary failed to implement this finding by requiring a performance standard, monitoring, and adequate medical surveillance which are mandated by the Act. On the performance standard issue, the Secretary restricted his consideration to the "no detectable level" standard proposed by petitioners and later recommended by the advisory committee (*Id.* at 20a-21a). He never addressed his general obligation to set a performance standard,

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[8] The advisory committee met for eighteen days and considered evidence from government agencies and other experts, including extensive presentations from industry.

whether at the zero level or some other level — a failure which is exemplified by the absence of any discussion of the section 6(b)(5) preference, if not a requirement, for performance standards.

Having failed to establish a definite limit on worker exposure, the Secretary further eroded worker protection by omitting any requirement that employers monitor the workplace to detect the amount of the carcinogen to which workers are exposed. In a brief two sentences the Secretary dismissed his statutory responsibility to prescribe monitoring, and merely referred the development of a monitoring requirement to NIOSH, an agency over which he has no control, 29 U.S.C. §§671(a), 671(b), and imposed no time limits on the receipt of NIOSH's work.[9]

Finally, having failed to insure adequate control of worker exposure by refusing to set a performance standard, and having refused to provide monitoring to determine the extent of worker exposure, the Secretary issued totally inadequate requirements for medical surveillance. Instead of prescribing specific tests to detect particular forms of cancer caused by different carcinogens, the Secretary left the selection of the techniques entirely to the employers. In spite of the Secretary's admission that specific medical surveillance was necessitated by the long latency period

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[9] In turn, NIOSH signed an interagency agreement on May 20, 1974, with the former Atomic Energy Commission to develop monitoring techniques. This agreement is not scheduled for completion until September 30, 1976 — a full two and a half years after the issuance of the permanent standards. U.S. Dep't of Health, Education & Welfare, Nat'l Inst. for Occupational Safety & Health, *Interagency Agreement #NIOSH-IA-74-35* at 7 (1974).

between a worker's first exposure to the carcinogen and the first appearance of cancer (App. B, p. 20a), the advisory committee recommendations were ignored entirely. Once again, the statement of reasons reflects no concern for the statutory obligation to specify the contents of the required medical examinations and diagnostic tests.

In sum, while the finding by the Secretary that the fourteen chemicals presented grave dangers of inducing cancer suggested the need for stringent measures to protect the workers, the Secretary's standards fell far short of the minimum requirement under the Act that the standards ". . . most adequately assure that no employee will suffer material impairment of health . . ." as a result of exposure to these carcinogens. Section 6(b)(5), 29 U.S.C. §655(b)(5).

B. The Decision of the Court of Appeals

Once again petitions for review were filed in the Third Circuit by the employers who used chemicals found to be carcinogens. This time, however, there were challenges not only to EI and DCB, but also to CCME and MOCA.[10] Petitioners once again filed for review under section 6(f) of the Act, 29 U.S.C. §655(f), raising substantially the same objections to the permanent standard that they had presented to the Third Circuit on the emergency standard and to the Secretary and the advisory committee during the proceedings on the permanent standard. At the request of the employers who utilized EI, that petition for

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[10] CMME is the acronym for methyl chloromethyl ether and MOCA® is the registered trade mark for 4,4'-methylene bis (2-chloroaniline).

review was severed from the remainder of the case, and an expedited schedule was ordered. Before the argument was held on the remaining cases, the Court of Appeals affirmed the determination of the Secretary that EI was a carcinogen, but reversed the part of the standard relating to its use in laboratories and remanded that matter for further proceedings. *Synthetic Organic Chemical Mfrs. Ass'n v. Brennan*, 503 F.2d 1155 (3d Cir. 1974), *cert. denied*, ____ U.S. ____, 95 S.Ct. 1396 (1975).

Thereafter, on December 17, 1974, a different panel of the Third Circuit affirmed the Secretary's determination that the other three chemicals whose carcinogenicity was being contested also presented a significant risk of cancer to humans exposed to them. (App. A, pp. 3a-5a). However, the Court concluded that the Secretary had not followed the statutory procedures and timetable for utilization of advisory committees and hence the standard dealing with MOCA — the only chemical as to which the objection was raised — was "... remanded to the Secretary for compliance with the statutory mandate." (App. A, p. 5a).

The Court then turned to its review of the portions of the standards which petitioners claimed to be insufficient to protect exposed workers and to be in violation of various provisions of the Act. Initially it considered the Secretary's failure to prescribe a performance standard. Like the Secretary, it made the fundamental error of restricting its examination to whether a particular performance standard — one requiring "no measurable exposure" — was appropriate, rather than deciding whether the Secretary erred in omitting any performance standard, be it at zero tolerance or some other level of exposure. Having so limited the issue, and without reference to the contrary recommendation of the advisory committee, the Court concluded that

the Secretary's decision was ". . . a reasonable exercise of judgment in the policy-making sphere." (App. A, p. 10a). In its brief discussion of the question, section 6(b)(5), which directs the Secretary to utilize a performance standard, was neither cited nor discussed by the Court.[11]

The next deficiency in the standard was also brushed aside by the Court quite quickly. Although the standard lacked any monitoring to detect worker exposure to these carcinogens, the Court sustained the Secretary's decision to request another agency to develop methods for determining amounts of carcinogens in the workplace (App. A, p. 11a). Unable to find any explanation for this buck-passing in the statement of reasons, the Court explained it by restating what the Secretary had done: ". . . in effect the Secretary has deferred implementation of monitoring requirements pending further development of methods for doing so . . . ." (*Id.* at 12a). The Court ignored entirely the monitoring recommendations of the advisory committee,[12] the Secretary's own compilation of available monitoring techniques,[13] and the broad statutory

[11] The Act also directs the Secretary to consider ". . . experience gained under this and other health and safety laws . . . ." 29 U.S.C. §655(b)(5). Performance standards known as "threshold limit values" had previously been set for all toxic substances regulated by the Secretary, 29 C.F.R. §§1910.93, Tables G-1, G-2 & G-3, 1910.93*a* (1974). Neither the Secretary nor the Court explained why this experience did not support the use of a performance standard in regulating these fourteen carcinogens.

[12] 38 *Fed. Reg.* 24377 (September 7, 1973).

[13] Occupational Safety and Health Administration, U.S. Dep't of Labor, *Supplement to Final Environmental Impact Statement on Proposed Regulation: Handling of Certain Carcinogens* 63-66 & Tables I-III (filed December 3, 1973).

authorization to act on the basis of the "best available evidence" and the "latest available scientific data in the field," 29 U.S.C. §655(b)(5). And, most importantly, the Court again failed to consider the governing statutory mandate to provide ". . . monitoring or measuring exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees . . . ." 29 U.S.C. §655(b)(7).

Finally, the Court confronted the inadequate medical surveillance required by the standard. This time, however, the Court was not satisfied with the Secretary's failure ". . . to explain the lack of specific requirements making the medical examinations effective . . ." (App. A, p. 13a), and this dissatisfaction led it to compare the standard to the advisory committee recommendations. (*Id.* at 12a). It also noted but did not comment or rely on the requirement of section 6(b)(7), which directs the Secretary ". . . to prescribe the type and frequency of medical examinations . . . to most effectively determine whether the health of such employees is adversely affected by such exposure." (*Id.*) Based on this analysis, it found the standard to be inadequate. The Court remanded because "[t]he Secretary gave no reasons for ignoring this recommendation of the advisory committee, nor did he indicate, as he did in connection with monitoring devices, that further information was needed." (*Id.*) But even in this action, reversing the Secretary's determinations concerning medical surveillance, the Court of Appeals fell into the same error as on the other two points: it judged the standard by whether the Secretary's action appeared reasonable and not by whether it was within the statutory guidelines set forth in sections 6(b)(5) and 6(b)(7) of the Act.

REASONS FOR GRANTING THE WRIT

A. The Decision Below Violates the Duty of Appellate Courts to Review Questions of Law and Thus Seriously Compromises the Basic Protections Afforded Workers by the Act.

The failure of past efforts to eliminate serious workplace hazards prompted Congress to pass the Occupational Safety and Health Act of 1970. In it Congress sought to eradicate a nation-wide epidemic which caused 14,500 deaths and disabled 2.5 million workers each year. S. Rep. No. 91-1282, 91st Cong., 2d Sess. 2 (1970) (hereafter "Senate Report"). The objective of the Act is ". . . to reduce the number and severity of work-related injuries and illnesses, which despite current efforts of employers and government, are resulting in ever-increasing human misery and economic loss," Senate Report at 1. It intended to do this by providing every working man and woman a safe and healthful workplace. 29 U.S.C. §651(b).

Congress was also keenly aware of the 390,000 new cases of occupational disease each year. Senate Report at 2. The problems resulting from past inaction in regulating health hazards are compounded by the fact that ". . . every 20 minutes a new and potentially toxic chemical is introduced into industry . . ." *Id.* Furthermore, Congress found that over 65% of industrial workers were exposed to harmful physical agents or toxic materials. H.R. Rep. No. 91-1291, 91st Cong., 2d Sess. 15 (1970). Among these were the lung carcinogen asbestos and the bladder carcinogen beta-naphtylamine, Senate Report at 3-4, the latter being one of the fourteen carcinogens involved in these standards.

This serious public health problem could have been tackled by simply delegating broad rulemaking authority to the Secretary as Congress had done in the past. *E.g.*, Walsh-Healy Public Contracts Act, 38 U.S.C. §§35, 38. The House bill would have copied this former approach and would have left the Secretary unlimited discretion in regulating workplace hazards. H.R. 16785, 91st Cong., 2d Sess. §6 (1970) (engrossed bill).[14] However, the Senate insisted that the Secretary be directed to promulgate standards for toxic materials which ". . . most adequately assure . . . that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard . . . for the period of his working life . . ." S. 2193, 91st Cong., 2d Sess. §6(b) (1970). In addition, the Senate did not leave the Secretary free to formulate the contents of a standard without Congressional guidelines. The non-impairment rule was strengthened by directions to include specific provisions in each standard. Thus, section 6(b)(5) and 6(b)(7) required a performance standard, monitoring, and medical surveillance, as well as appropriate protective equipment, labels, and warnings. In each case the Senate's detailed directions were adopted in preference to the House bill which contained no comparable, specific provisions except for labels and warnings. H.R. Rep. No. 91-1795, 91st Cong., 2d Sess. 35 (1970). The result was a statute which contained not only a general admonition to the Secretary to protect the health of workers,

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[14] Senate Comm. on Labor & Public Welfare, *Legislative History of the Occupational Safety & Health Act of 1970*, 92d Cong., 1st Sess. 1094-1095 (1971).

but the equivalent of a check list of techniques which he was to utilize in most, if not all, the cases.[15]

Instead of reviewing the Secretary's action in terms of the controlling statutory mandates, the Court of Appeals merely looked to the statement of reasons. It then concluded that the Secretary's omission of a performance standard was a ". . . reasonable exercise of his judgment in the policy-making sphere" (App. A, p. 10a), and that the omission of a monitoring provision was a "pragmatic decision" (*Id.* at 12a). In neglecting to measure these standards in terms of their statutory framework, the court below significantly failed to perform the function assigned to it by Congress.

This Court has consistently maintained that the final authority to interpret Congressional enactments is vested in the judiciary, *United States v. American Trucking Ass'n*, 310 U.S. 534 (1940); *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803), even in those instances in which Congress has delegated legislative or adjudicatory functions to an administrative agency, *FTC v. Texaco, Inc.*, 393 U.S. 223 (1968); *National Broadcasting Co. v. United States*, 319 U.S. 190 (1943). This is particularly true

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[15] Each of these provisions contains such phrases as "whenever practicable" or "where appropriate" thus indicating that all of these standards, which cover safety hazards such as physical agents as well as these chemical carcinogens, need not contain all these provisions in every case. Nonetheless, a fair reading of these requirements indicates that inclusion is the general rule. In this case, the Secretary did not even explain his reasons for omitting these provisions. Yet, the Secretary is obligated to state the significant issues which have been faced and then articulate the rationale underlying their resolution, *Associated Industries of New York State v. U.S. Dep't of Labor*, 487 F.2d 342, 353-354 (2d Cir. 1974).

where statutory limitations are involved, *e.g., FMC Seatrain Lines, Inc.*, 411 U.S. 726 (1973), or where administrative action has been mandated by the statute, *Train v. City of New York*, ____ U.S. ____, 95 S.Ct. 839 (1975); *Train v. Campaign Clean Water, Inc.*, ____ U.S. ____, 95 S.Ct. 847 (1975). Where there is an administrative interpretation of statutory authority, the courts are ". . . not obliged to stand aside and rubber stamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the Congressional policy underlying a statute . . ." *N.L.R.B. v. Brown*, 380 U.S. 278, 291 (1965); *Volkswagenwerk Aktiengesellschaft v. FMC*, 390 U.S. 261, 272 (1968); *FMC v. Seatrain Line, Inc., supra*, at 746. Moreover, "[t]he deference owed to an expert tribunal cannot be allowed to slip into judicial inertia . . ." *American Ship Building Co. v. N.L.R.B.*, 380 U.S. 300, 388 (1965).

The reviewing court has an affirmative obligation to review administrative action regardless of the Secretary's failure, as in this case, to analyze his obligations in terms of the statutory mandate. The Court must delineate the scope of the Secretary's authority and discretion, and identify the range of choices left to the administrator by Congress. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415-416 (1971). Where there is little choice left to the administrator, the Court must carefully review compliance with the statutory requirements. *Id.* Judicial review thus necessitates a determination that the administrator's action conforms with the statutory mandates, *Train v. City of New York, supra*, and is consistent with the Congressional purpose, *Morton v. Ruiz*, 415 U.S. 199 (1974). Finally, the reviewing court must interpret the statute as mandatory when to do otherwise would

seriously impair the interests to be protected, *Escoe v. Zerbst*, 295 U.S. 490, 494 (1935).

Although section 6(b) dictates a limited range of choices for monitoring and a performance standard, the Court of Appeals has obliterated those limitations by failing to examine the statute at all. Instead, by concentrating its exclusive attention on the statement of reasons, it has abdicated the role assigned by Congress in reviewing the legal issues arising from the Secretary's interpretation, or more accurately, his non-interpretation, of the Act. The gravity of the abidcation of the Third Circuit is compounded here because these chemicals pose a cancer hazard to workers, and, as the Secretary himself acknowledged, there is no known safe level of exposure to these carcinogens (App. B, p. 20a).

The refusal of the Court of Appeals to at least insist on an explanation from the Secretary for not including these provisions is even less understandable in view of the wide spread practice of including performance requirements and monitoring in other standards issued under the Act, as the Secretary's own advisory committee recommended. For instance, the Secretary adopted as "established federal standards" under section 6(a) of the Act, 29 U.S.C. §655(a), nearly 400 performance standards for a variety of toxic substances that had originally been issued under the Walsh-Healy Act. 29 C.F.R. §1910.93, Tables G-1, G-2, & G-3 (1974). And in the first carcinogen standard promulgated under section 6(b), the Secretary included not only a performance standard, but also extensive monitoring provisions. 29 C.F.R. §1910.93*a*(b), (f) (1974) (asbestos).[16]

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[16] Subsequent to the issuance of the standards at issue here, the Secretary promulgated both emergency and permanent standards

(continued)

Because the court below failed to discharge its duty to review these standards in light of the requirements imposed by Congress, this Court should grant the writ and direct the Court of Appeals and the Secretary to consider the propriety of the standards under the tests established by the Act. In this way the health of the 10,000 employees affected by these chemicals will be protected in the manner provided by Congress, and the courts of appeals will be given specific guidance on the performance of their functions under the Act.[17]

B. This Court Should Settle A Critical Question Regarding Judicial Review of Occupational Safety and Health Standards On Which the Circuits Appear to Be in Conflict.

Three other circuits have been called upon to review the Secretary's actions in terms of the statutory requirements, and each has directly compared the action to the terms of the Act. In *Florida Peach Growers Ass'n v. U.S. Dep't of Labor*, 489 F.2d 120 (5th Cir. 1974), the Court enforced the section 6(c)(1) requirement that a "grave

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16 (continued)
for vinyl chloride which contain performance standards and a monitoring requirement. 29 C.F.R. §1910.93*q*(b), (c), 39 *Fed. Reg.* 12342 (April 15, 1974); 29 C.F.R. §1910.93*q*(c), (d), 39 *Fed. Reg.* 35890 (October 4, 1974).

17 The petition for certiorari denied by this Court with respect to the determination that EI was a carcinogen sought to question the approach of the Court of Appeals in applying the substantial evidence test to factual findings under section 6(f), 29 U.S.C. §655(f). Thus, that petition (No. 74-789) presented a very different type of issue from the one presented here.

danger" must support the issuance of an emergency temporary standard and required the Secretary to satisfy this statutory prerequisite. In another case involving the safety net standard, the Seventh Circuit directly applied the committee membership requirements of section 7(b) to the construction advisory committee even though it considered the petitioners' claims "frivolous." *National Roofing Contractors Ass'n v. Brennan*, 495 F.2d 1294 (1974), *cert. denied*, ____ U.S. ____, 95 S.Ct. 775 (1975). Significant issues were raised regarding the adequacy of the asbestos standard in another case, and the District of Columbia Circuit analyzed each in terms of the controlling statutory language. *Industrial Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467 (1974). And where it found that the Secretary failed to meet the requirements of section 8(c)(1) for the retention of monitoring records, that Court remanded the recordkeeping provisions to the Secretary. *Id.* at 485, 487-488. The Court also emphasized that the reviewing court must closely examine the Secretary's action in relation to the relevant concerns of the Act, *id.* at 488, and that it must determine whether the agency had performed in accordance with Congressional purposes. *Id.* at 475. Finally in *Associated Industries of New York State v. U.S. Dep't of Labor*, 487 F.2d 342, 353-354 (2d Cir. 1973), Judge Friendly followed the same basic approach in reviewing the lavatories standard.

Although the Third Circuit in two earlier decisions,[18] and in the part of this decision dealing with the timing of the proposed permanent standard on MOCA (App. A, pp. 5a-9a), reversed decisions of the Secretary, it did so on procedural

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[18] *Dry Color Mfrs. Ass'n v. Dep't of Labor, supra; Synthetic Organic Chemical Mfrs. Ass'n v. Brennan, supra.*

matters that could be readily cured upon remand. However, when the Court came to the substantive mandates for worker protection, it ignored both the controlling statutory mandates and its past precedents enforcing procedural mandates. Indeed, even its reversal on the issue of medical surveillance was based almost entirely on the irrationality of the Secretary's action and not on the dictates of the Act.

C. This Court Should Settle A Critical Question of Statutory Construction Involved In the Administration and Enforcement of the Act.

Worker protections meeting the basic statutory mandates will be a central issue in setting all future health standards under the Act. The fourteen standards involved in this petition are the forerunners of hundreds of other standards which will be necessary to control workplace hazards. The most recent NIOSH *Toxic Substances List* includes 13,000 chemicals which have demonstrated toxic effects,[19] and new chemicals are constantly being introduced into the marketplace. Senate Report at 2.

Formal recommendations for 20 new standards ("criteria documents") have been transmitted to the Secretary from NIOSH and are awaiting standard-setting action, with an estimated 18.5 million workers who must confront these serious health hazards.[20] Another 31 criteria documents

19 Nat'l Inst. for Occupational Safety & Health, U.S. Dep't of Health, Educ. & Welfare, *The Toxic Substances List — 1974 Edition* vii.

20 Nat'l Inst. for Occupational Safety & Health, U.S. Dep't of Health, Educ. & Welfare, *Criteria for Recommended Standards on Occupational Exposure to Ammonia, Inorganic Arsenic, Benzene,* (continued)

are expected before the end of fiscal year 1976,[21] and NIOSH has recently begun an inquiry into the dangers of 29 other chemical substances.[22] However, planned government projects will not be the only source of new standards in the future, as evidenced by the unexpected disclosure of new hazards for both vinyl chloride[23] and arsenic.[24]

Every new standard will necessarily involve the statutory requirements for a performance standard, monitoring, medical surveillance, and the other mandates of section 6(b)(7). Furthermore, in the next two years almost 400 "established federal standards" promulgated in 1971[25] will be supplemented with the monitoring, medical surveillance, and other requirements under section 6(b)(7) that they now lack.[26]

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20 (continued)
Beryllium, Carbon Monoxide, Chloroform, Chromic Acid, Coke Oven Emissions, Cotton Dust, Crystalline Silica, Hot Environments, Inorganic Lead, Inorganic Mercury, Noise, Sulfur Dioxide, Sulfuric Acid, Toluene, Toluene Diisocyanate, Trichloroethylene, & Ultraviolent Radiation (1972-1975).

21 3 CCH Employment Safety & Health Guide ¶9545 (1975).

22 39 *Fed. Reg.* 44792 (December 27, 1974); 40 *Fed. Reg.* 7960 (February 24, 1975); 40 *Fed. Reg.* 13231 (March 25, 1975).

23 39 *Fed. Reg.* 3874 (January 30, 1974) (fact-finding hearing); 39 *Fed. Reg.* 12342 (April 15, 1974) (emergency temporary standard).

24 39 *Fed. Reg.* 31644 (August 30, 1974) (fact-finding hearing); 40 *Fed. Reg.* 3392 (January 21, 1975) (proposed permanent standard).

25 36 *Fed. Reg.* 10466, 10503-10506 (May 29, 1971).

26 Notices of proposed rulemaking appear at 39 *Fed. Reg.* 33843 (June 20, 1974); 40 *Fed. Reg.* 4019 (January 27, 1975); 40 *Fed. Reg.* 4930 (February 3, 1975); 40 *Fed. Reg.* 11890 (March 14, 1975); 40 *Fed. Reg.* 17654 (April 21, 1975); 40 *Fed. Reg.* 20201 (May 8, 1975).

The issues raised in this petition regarding judicial review and the worker protections required by the Act, will have universal application to this enormous standard-setting activity. Resolution of these statutory issues by this Court will assist the Secretary in meeting his statutory obligations and guide the courts of appeals in reviewing these standards.

Finally, occupational health and safety standards are the primary enforcement method under the Act, *Brennan v. Occupational Safety & Health Review Comm'n*, 491 F.2d 1340, 1343 (2d Cir. 1974). Where a standard lacks protective provisions such as monitoring or medical surveillance, compulsory enforcement of these protections under sections 9 and 10 of the Act will be extremely difficult. *See generally, American Smelting & Refining Co. v. Occupational Safety & Health Review Comm'n*, 501 F.2d 504 (8th Cir. 1974). Even employer efforts at voluntary compliance are seriously compromised when the standard lacks any specific guidance on worker protections.

The cancer hazard posed by these fourteen chemicals immediately affects ten thousand workers. However, the necessary protection of the 57 million workers covered by the Act is directly dependent on the promulgation and enforcement of standards which afford the complete protection mandated by Congress. This Court, by reviewing the decision below and directing the Secretary and the courts of appeals to comply with the Act, can significantly advance the effectiveness of the worker protection provided by Congress and give badly needed guidance to all concerned and thereby avoid unnecessary litigation.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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May 16, 1975

APPENDIX A

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 74-1129
No. 74-1149
No. 74-1268

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, ET AL.,
Petitioners in No. 74-1129

v.

PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR, ET AL.,
Respondents.

OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO, ET AL.,
Petitioners in No. 74-1149

v.

PETER J. BRENNAN, SECRETARY, DEPARTMENT OF LABOR, ET AL.,
Respondents.

POLYURETHANE MANUFACTURERS ASSOCIATION,
Petitioner in No. 74-1268

v.

DEPARTMENT OF LABOR, ET AL.,
Respondents

ON PETITION FOR REVIEW OF ACTION OF THE ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH

Argued October 21, 1974

Before HASTIE, GIBBONS and WEIS, *Circuit Judges.*

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OPINION OF THE COURT

(Filed December 17, 1974)

WEIS, *Circuit Judge.*

The important subject of OSHA's regulations on the usage of a group of chemicals labeled as carcinogens occupies us once again. Although most of the standards are sustained, those as to laboratory practices and medical examinations of employees must be remanded. We also find validity in the objections by one of the appellants that the Secretary of Labor erred in not publishing a proposed regulation after receiving the report from his advisory committee.

These are companion cases to *Synthetic Organic Chemicals Manufacturers Association v. Brennan*, — F.2d — (No. 74-1129 3d Cir. Aug. 26, 1974), consisting of appeals from occupational health standards promulgated by the Secretary of Labor. These permanent regulations were issued on January 29, 1974, regulating, *inter alia*, the exposure of employees to fourteen chemicals found to be carcinogenic. 29 C.F.R. § 1910.93c-p.

Appeals to this court were filed on behalf of employers who utilized four of the chemicals—EI, CMME, DCB and MOCA. Another appeal was filed by the Oil Chemical and Atomic Workers Union from the standards applicable to all fourteen substances. The appeal as it pertained to Ethyleneimine (EI) was severed, and we held in the prior opinion that the Secretary had made sustainable determinations as to the chemical's carcinogenicity and proper standards for industrial usage. We concluded, however, that proper notice had not been given before promulgating regulations for the use of EI in the laboratory and remanded on that point. Our conclusions as to the legal issues presented by the earlier case likewise apply to the appeals now under consideration and we need not repeat what was said in our prior opinion.

The contentions made here with respect to 3, 3'-dichlorobenzidine (DCB) by employers who utilize it are similar to those raised in connection with EI—that is, the data derived from tests revealing carcinogenicity in animals were not properly extrapolated to human susceptibility. Nothing in the record permits a differentiation here from our earlier decision on EI, and we do not make one. While the scientific data varies, of course, the same legal principle applies and, accordingly, the petitioners' contention must fail.

The thrust of the opposition to the standard regulating chloromethyl methyl ether (CMME) is aimed at certain studies relied upon by the Secretary. The employers contest the validity of the Van Duuren studies[1] by questioning whether pure CMME was tested or whether, as usually occurs, the substance was contaminated to form bis chloromethyl ether (BCME).[2] Again, the issue is the same as that in the EI appeal, and again in this case the Secretary's determination finds adequate support in the record.

Polyurethane Manufacturers Association (PMA), the employers' association concerned with the use of 4,4' methylene bis (2-chloroaniline) (MOCA)[3] in various manufacturing processes, presses the same arguments as to carcinogenicity that are advanced for DCB and CMME. Of necessity, the same criteria of review is applied to this chemical as the others in question. The Secretary's deter-

1. Van Duuren studied the properties of BCME and CMME and, in 1968, produced the first evidence for the carcinogenicity of these halo-ethers. His experiments employing both skin applications and subcutaneous injections led to the conclusion that, in the presence of certain other re-agents, and under some circumstances acting alone, CMME and BCME caused lesions in animal subjects. In each instance, Van Duuren verified the purity of the CMME used through I.R. and GLC analysis, showing no BCME content.

2. BCME is a potent chemical which industry concedes is carcinogenic. It appears that at the present time production of pure CMME is not commercially feasible. In industrial usages, it rapidly decomposes in air and aqueous solutions to form BCME and, therefore, there is no widespread usage of pure CMME now.

3. MOCA is the trade name utilized by duPont, although the same chemical is used by other industrial chemical concerns. We use the MOCA trade name because of its simplicity, but it should be understood that we are referring to the chemical, 4,4' methylene bis (2-chloroaniline).

mination is supported by the record and therefore must be sustained.

PMA, however, raises one additional contention not presented in the other appeals. It challenges the procedures followed by the Secretary in promulgating the permanent standards for the industrial use of MOCA. This contention has merit and requires that the case be remanded to the Secretary for compliance with the statutory mandate.

MOCA was subject to the same emergency standard that was issued by the Secretary for the other thirteen chemicals on May 3, 1973 although PMA apparently did not become aware that MOCA was to be included in the group until the emergency standard was published. Thereafter, the Secretary instituted procedures to enact a permanent standard. According to 29 U.S.C. § 655(c)(2) and (3), once an emergency temporary standard is enacted, it is effective until superseded by a permanent standard fashioned in accordance with the procedures prescribed in § 655(b). The emergency standard serves as a proposed rule for that proceeding and the permanent standard must be enacted within six months. The legislative history emphasizes that "upon publication of such an emergency temporary standard, the Secretary must begin a regular standard setting procedure." 1970 *United States Code Congressional and Administrative News*, P. 5184.

We now turn to the requirements of § 655(b). That section provides that the Secretary may request the recommendations of an advisory committee to which he may submit his own proposals as well as pertinent factual and research data. The committee then submits its recommendations to the Secretary within a specified time. Paragraph (2) provides that the Secretary shall publish a proposed rule and that interested parties be given the opportunity to submit written data, comments or objections to the proposal within thirty days. If an advisory committee has been appointed, the Secretary is to publish the

proposed rule within sixty days after the submission of the committee's recommendations. Paragraph (3) provides that, if objections are filed to the proposed rule and a hearing is requested, notice of the hearing shall be given within thirty days of the last date for filing objections.

With these guidelines in mind, it is appropriate to review the chronology of the proceedings here:

May 3, 1973	—The emergency temporary standard was issued.
June 19, 1973	—The Secretary announced the formation of an advisory committee.
July 16, 1973	—The Assistant Secretary of Labor published a notice of "Commencement of rule-making proceeding," stating that the emergency standard of May 3, 1973 was proposed to be made permanent.
July 27, 1973	—The Assistant Secretary published a revision of the emergency temporary standard.
August 16, 1973	—An amended notice of proposed rule making was published to reflect the revision.
August 27, 1973	—The advisory committee submitted its recommendation to the Secretary.
September 7, 1973	—The committee's recommendations were published.
September 11-14, 1973 [4]	—Public hearings were held. Additional comments were received until September 28, 1973.

4. On September 6, 1973, PMA sent a telegram to the Assistant Secretary of Labor urging that the hearing set for September 11 be cancelled and requested that a proposed rule be published pursuant to § 655(b)(2) together with an allowance of thirty days to file comments.

January 29, 1974 —The permanent standard was published as to MOCA, with separate regulations for the thirteen other substances.

The procedures followed here did not comply with § 655(b). The proposed rule was published before the advisory committee had submitted its report. Consequently, the parties were not given adequate time to submit comments or to prepare for the hearing after the committee's work was completed. Had § 655(b) been observed, under the most expeditious of circumstances, the hearing could not have been held earlier than thirty days after the advisory committee had submitted its report to the Secretary.[5]

The Secretary contends that this timetable does not apply when an emergency standard has been issued since § 655(c)(3) states that the emergency standard shall serve as a proposed rule for the paragraph (b) proceeding. If no advisory committee is appointed, paragraphs (b) and (c)(3) are consistent but when an advisory committee does function, there is a conflict between the two statutory provisions. It is our conclusion that paragraph (b) must prevail. As we said in *Dry Color Manufacturers' Association v. Department of Labor*, 486 F.2d 98, 104-105 n.9a (3d Cir. 1973):

> "The courts should not permit temporary emergency standards to be used as a technique for avoiding the procedural safeguards of public comment and hearings required by subsection 6(b). Especially where the effects of a substance are in sharp dispute, the promulgation of standards under subsection 6(b) is preferable since the procedure for permanent standards is specifically designed to bring out the relevant facts."

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5. This schedule assumes that the Secretary published the rule on the same day that he received the recommendations of the advisory committee. Obviously, if he is to give any consideration to the advisory committee report, the period must be longer. In the cases at bar, only four days elapsed between the dates of publication and hearing.

While that comment was made in another context, its underlying philosophy is pertinent.

If we were to hold that paragraph (b) does not apply, then the purpose of convening an advisory committee would be subverted. A rule which the committee was to assist in formulating would have already been published and the committee's function would be reduced to merely preparing comments to a proposal. This is not compliance with the statutory mandate that the committee shall submit its recommendations "regarding the rule to be promulgated." Congress did not intend a mere post facto role for the advisory committee because it provided that a proposed rule must be published within sixty days after submission of the committee's recommendation. § 655(b)(2).

We are not critical of the Secretary's decision to utilize an advisory committee in this instance. To the contrary, in view of the complexity of the problems, that procedure is highly desirable. *See* 1 Davis, *Administrative Law Treatise* § 6.03. However, the value of notice and comment from interested parties in a hearing for rule making was not realized in this case. As an example, the advisory committee was instructed that only one set of standards would be promulgated for all fourteen chemicals, despite the substantial differences in their properties and their industrial and laboratory uses.[6] After the public hearings had been concluded, however, the Secretary issued separate standards for each chemical.[7] Had the proposed rule recited the separate standards, the presentation of pertinent objections, comments and data would have made the public hearings far more valuable to all concerned.[8] Since the

6. Some of the committee members objected to this directive and the Secretary recognized that there was some merit to their position by publishing a revision of the emergency temporary standard on July 27, 1973. 38 Fed. Reg. 20074 (1973). However, this revision did little to solve the problem and the instructions to the committee remained unchanged.

7. Much of the language, however, in the separate standards is merely duplication of that governing all of the other chemicals.

8. PMA, for example, says that the revision of July 27, 1973 permitted it to utilize open vessel processes. However, the report of the advisory com-

procedural requirements of the statute were not observed, the standards relating to MOCA must be remanded to the Secretary for appropriate action to correct the defects.

The Oil Chemical and Atomic Workers Union (OCAW) and the Health Research Group have appealed from the standards established for each of the fourteen chemicals. These petitioners assert that the standards are deficient because:

1. they fail to include a performance standard mandating no measurable exposure to any of the chemical substances;
2. the Secretary erred in declining to require a permit system as a regulatory device;
3. no monitoring requirements were included in the final regulation; and
4. no specific tests were set forth as part of the requirements for medical examinations.

The first contention, suggesting that a no measurable exposure standard be used, presents the same difficulty in review as that discussed in the EI case. There, we pointed out that by extrapolating the testing on animal species to establish carcinogenicity in man, the Secretary was exercising a policy judgment rather than a purely factual determination.

Here, the Secretary stated that, while a safe level of exposure cannot be established by application of present

8. (Cont'd.)
mittee, whose recommendations had to be geared to cover all fourteen chemicals, permitted only closed vessel operation. The permanent standards prohibited open vessel operation. The Secretary contends that the revised definition of "closed vessels" formulated by the advisory committee and ultimately adopted in the permanent standard does permit certain open vessel operations involving MOCA. PMA questions this and asserts that had it been given the opportunity to meet the issues at a public hearing after being advised of the specific standard later adopted, it would have been able to develop the data to show that the unique properties of MOCA would permit safe operation in open vessels. We do not resolve that factual dispute here and merely point to it as an example of where compliance with the terms of the statute might have provided a regulation and standard more acceptable to all concerned.

knowledge, there is respectable opinion that such levels do exist and that a total ban on manufacture is the only complete guarantee of no possible exposure.[9] He recited that the intent of the standards is to reduce exposure of workers to the maximum extent practicable with continued use. The standards applicable to certain of the substances do provide that mixtures containing less than one percent of the chemical would be exempt from regulation and in the other six the level is set at 0.1 percent.

As was aptly stated in *Industrial Union Department v. Hodgson*, 499 F.2d 467, 474 (D.C. Cir. 1974):

> ". . . some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis."

And in discussing the requirements of feasibility noted in § 655(b)(5),[10] the court said:

> "Congress does not appear to have intended to protect employees by putting their employers out of business—either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible."

We conclude that the action of the Secretary in setting exposure standards is a reasonable exercise of his judgment in the policy making sphere.

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9. 39 Fed. Reg. 846 (1974).

10. This section in part provides, "The Secretary . . . shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health . . ."

While the advisory committee recommendation favored a permit system,[11] the Secretary stated that a decision had been made not to adopt such a system. He wrote:

> "The investigations and evaluations of thousands of work situations involving a carcinogen, and the completion of procedures, possibly including hearings, for the granting of permits, would require many years and the diversion of substantial resources, even if available, from other serious occupational safety and health considerations." [12]

Though there is much to be said for recently expressed concern about undue judicial deference to administrative expertise, this is an appropriate situation for such respect. The OSHA program is a vast one, but to interested parties one particular facet of its operation may understandably appear to be the most critical. The Secretary, however, who has the responsibility for allocation of the not unlimited resources entrusted for OSHA's operation, may differ. The court should defer to his opinion of what is a practical program which can be administered with some degree of speed and efficiency. We find no error in the Secretary's choice between methods of enforcement.

No provision for specific techniques of environmental monitoring are contained in the standards and OCAW objects to this omission. But in our view the Secretary has satisfactorily met this objection by requesting NIOSH [13] to develop, on a priority basis, methods for determining amounts of carcinogens in the work place. In effect the

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11. An employer would be required to apply to the agency for a permit before being allowed to use the chemical. The permit would presumably not issue until there was a showing of compliance with appropriate standards. This type of regulation should be contrasted with the one put into effect, that is, permitting usage, but depending for enforcement upon inspections and sanctions for non-compliance.

12. 39 Fed. Reg. 846 (1974).

13. The National Institute for Occupational Safety and Health (NIOSH) was established within the Department of Health, Education and Welfare by 29 U.S.C. § 671.

Secretary has deferred implementation of monitoring requirements pending further scientific development of methods for doing so. Such a decision is a pragmatic one which will not be disturbed by the court.

Finally, OCAW attacks the provisions for medical examinations because they do not prescribe specific medical protocols and diagnostic tests to be given employees who work with the chemicals. The advisory committee suggested that employers should provide a comprehensive history and physical examination consisting of diagnostic tests and periodicity specific to the carcinogen and in no less detail than guidelines set forth by the Secretary of Labor after consultation with the Secretary of Health, Education and Welfare.

During the rule-making process, evidence was submitted which established that the various carcinogens acted on different bodily organs and that particular tests were required for specific chemicals. This evidence was another instance of the problems engendered by considering all of the substances as a group rather than on an individual basis.

The Secretary gave no reasons for ignoring this recommendation of the advisory committee, nor did he indicate, as he did in connection with monitoring devices, that further information was needed.

29 U.S.C. § 655(b)(7) provides, *inter alia:*

> "In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure."

In contrast to the standards adopted here, certain diagnostic tests are required by the regulations pertaining to asbestos workers, *see* 29 C.F.R. § 1910.93a(j)(2) & (3), and

some specificity is evident in the medical examination requirements for employees who are exposed to vinyl chloride, 39 Fed. Reg. 35897 (1974).

At oral argument, counsel for the Secretary posited that the existing broad standards could be interpreted to require any specific diagnostic tests which might be necessary. But this approach introduces an element of uncertainty not satisfactory to either employee or employer. It is important that the worker be assured of the benefits of medical procedures that are presently available and that industry be advised of what is expected of it. The regulations can be drafted with ample flexibility to take advantage of expanding medical knowledge in the field. Specific provisions need not discourage improvement or innovation in this critical area.

The failure of the Secretary to explain the lack of specific requirements making the medical examinations effective requires that we remand this aspect of the standards applicable to all of the chemicals.

In summary then, the regulations applicable to 4,4′ methylene bis (2-chloroaniline) (MOCA) will be remanded for the publication of a proposed standard, to be followed by the required procedures for allowance of comments and hearing. The regulations pertaining to laboratory usage of all the chemicals involved in these appeals are remanded so that appropriate notice may be issued to interested parties and opportunity provided for comment and hearing. The portion of the standards applicable to all of the chemicals referring to medical examinations will be remanded for further proceedings.

A True Copy:

Teste:

Clerk of the United States Court of Appeals for the Third Circuit.

(A.O.—U. S. Courts, International Printing Co., Phila., Pa.)

APPENDIX B

STATEMENT OF REASONS AND A REPRESENTATIVE CARCINOGEN STANDARD ISSUED BY SECRETARY OF LABOR JANUARY 29, 1974

The Statement of Reasons and Standards on Carcinogens issued by the Secretary of Labor, 29 C.F.R. §§ 1910.93*c-p*, 39 *Fed. Reg.* 3756 (January 29, 1974), are reprinted below. A representative standard has been selected, 29 C.F.R. § 1910.93*l*, since all fourteen standards are identical for the purposes of this petition.

TITLE 29—LABOR

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Carcinogens

Pursuant to section 6(b) and (c) of the Williams-Steiger Occupational Safety and Health Act of 1970 (29 U.S.C. 655) and Secretary of Labor's Order No. 12-71 (36 FR 8754), Part 1910 of Title 29, Code of Federal Regulations, is hereby amended in the manner set forth below, in order to provide standards dealing with the exposure of employees to certain substances that are known to cause cancer.

Background. On May 22, 1972, the Deputy Assistant Secretary of Labor for Occupational Safety and Health requested information from the Director of the National Institute for Occupational Safety and Health (NIOSH) on nine substances alleged to be carcinogens. As part of his effort to gain the best available scientific data, the Director published on July 6, 1972, at 37 FR 13285, a request for information concerning 15 substances. The data, arguments, and conclusions received by NIOSH were made available to the Occupational Safety and Health Administration.

On January 4, 1973, a petition for an emergency temporary standard from the Oil, Chemical, and At-

omic Workers Union (OCAW) and Health Research Group (HRG) was received by the Department of Labor. The petition contained relevant information on the danger of exposure to 10 carcinogens, and suggested regulations to prevent worker exposure to the substances.

On February 9, 1973, a notice was published in the FEDERAL REGISTER (38 FR 4037) of the receipt of the petition for issuance of an emergency temporary standard, and information was requested from interested persons on the issues involved. In response to the notice, more than 50 written comments were received.

An emergency temporary standard on carcinogens was promulgated on May 3, 1973, at 38 FR 10929. The standard concerned work practices and controls designed to protect employees from exposure to 14 carcinogenic substances.

A standard advisory committee on carcinogens was appointed and began its meetings on June 25, 1973. The members of the committee represented employers, employees, Federal and state agencies and professionals. The committee terminated its meetings on August 24, 1973, and submitted to the Assistant Secretary of Labor for Occupational Safety and Health its recommendations for a standard on certain carcinogens on August 27, 1973. The recommendations were published in the FEDERAL REGISTER on September 7, 1973 (38 FR 24375).

This rulemaking proceeding was commenced under section 6(b) and (c) of the Act, with the emergency temporary standard serving as a proposal as required by section 6(c)(3) of the Act. Notice of the proceeding was published in the FEDERAL REGISTER on July 16, 1973 (38 FR 18900). On July 27, 1973, a revision of the emergency temporary standard was published at 38 FR 20074, and an amended notice of rulemaking pro-

ceeding was published at 38 FR 22141, on August 16, 1973.

The notices invited interested persons to submit, prior to September 5, written comments, data and arguments concerning the proposals, and also provided for the presentation of oral testimony at a public hearing scheduled for September 11-14, 1973. Numerous written comments were received and about 36 parties testified at the hearing. The record of the hearing was initially held open until September 28, for additional comments. After the close and certification of the record by the administrative law judge, additional comments mailed on or before September 28 were received. On October 2 the judge reopened the record for the limited purpose of including these additional comments. On October 15, the judge closed the proceeding and forwarded the certified record to the Assistant Secretary of Labor for Occupational Safety and Health for final decision.

A final environmental impact statement on the proposed standard on carcinogens was filed with the Council on Environmental Quality on October 2, 1973, and copies were distributed to appropriate agencies. In a letter dated November 2, 1973, the Council pointed out alleged deficiencies in the statement filed. Pursuant to that letter, a supplement to the statement was sent to the Council on November 29, 1973, with a request for a waiver of the full, 30-day review period. By letter dated December 10, 1973, the Council advised that the request had been denied. Notice of the filing of the supplement was published by the Council on December 14, 1973 (38 FR 34488).

The following are the major issues raised in the record of this proceeding:

(1) *Selection of carcinogens.* Some participants in this proceeding have demanded to know the criteria

for the selection of the 14 substances for regulation. As the written submission of Uniroyal Chemical notes, thirteen compounds derive from Appendix A to the 1972 TLV pamphlet published by the American Conference of Government Industrial Hygienists (ACGIH). Alpha-Naphthylamine, which is not in the appendix, has been added because it has frequently been found, in industrial experience and in epidemiologic studies, together with beta-naphthylamine, and because experimental animal studies demonstrate its independent carcinogenicity, Dimethyl sulfate, which is in the appendix, is not included in the standards because it was concluded after consideration of the relevant literature that the documentation of its carcinogenicity was inadequate. The substances listed by ACGIH (except one) were selected in order to take advantage of the work and judgment of that group. Also, ten of the fourteen substances were proposed to the Occupational Safety and Health Administration (OSHA) for regulation by OCAW and HRG in their petition.

(2) *Documentation of carcinogenicity.* The National Institute for Occupational Safety and Health (NIOSH), as official scientific advisor to OSHA, submitted to OSHA fourteen hazard review documents; one for each of the substances included in the standards. Each hazard review document contains a summary and evaluation of information and data obtained by NIOSH, including experimental animal and epidemiologic data. All but one of the substances are considered by ACGIH to be carcinogenic in man and/or animals.

In promulgating these standards, OSHA has relied extensively but not exclusively, on the hazard review documents prepared by NIOSH. Some of the substances are recognized as human carcinogens by some employers participating in this proceeding. For in-

stance, although Young Aniline Works apparently takes issue with the studies which demonstrated Benzidine to be a human carcinogen, the Benzidine Task Force of the Synthetic Organic Chemical Manufacturers Association does not oppose OSHA considering benzidine as carcinogenic to humans.

The essence of the NIOSH hazard review documents follows.

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Ethyleneimine. The carcinogenic potential of ethyleneimine (EI) has been confirmed by a study conducted by Walpole in 1954 involving rats and one sponsored by the National Cancer Institute involving mice. In the first study, animals developed injection site sarcomas which the investigators attributed to the direct action of Ethyleneimine, and in the second study 80 percent of the animals developed tumors, including more than one-half with hepatomas (which the investigators stated had "malignant potentiality") and almost three-quarters with pulmonary tumors. Although high doses of EI were administered, the investigators stated there was no way to predict whether man would be more or less susceptible to tumor induction by EI.

The case for the carcinogenicity of EI, then, rests on the extrapolation to humans of the findings in two separate, controlled animal studies. This position is compatible with that of NIOSH concerning the prior demonstration of carcinogenicity in at least two animal studies.

A major question of occupational carcinogenesis relates to the extrapolation of results of animal experimentation to humans. The basis of numerous objections to the proposals is that, even assuming the validity of animal experiments, such do not furnish sufficient evidence that the substances involved are carcinogenic to humans. Extrapolation of results

obtained by animal experimentation is alleged to be vitiated by several considerations: (a) That certain cancers are specific only to some species; (b) that the conditions of animal experiments are out of proportion to, and not consistent with, conditions prevailing in industrial exposure; and (c) that no cancers have yet been detected in humans exposed to the substances. For those substances whose metabolism is understood, and is similar in both animals and man, the fact that they induce cancers in animals warrants the expectation that they will induce cancers in men. This applies to the substances which cause urinary bladder cancers in animals acting, not directly, but indirectly through the mediation of metabolites formed both in experimental animals and in exposed workers. This is also true of those substances which apparently require no metabolic alteration but attack a particular biologic system (e.g., respiratory tract, alimentary canal) which is similar in both animals and humans.

The objections raise the much broader issue of human exposure to a chemical which is only known to have caused cancers in experimental animals.

It is important to note that some opponents of the regulation of such chemicals do not advocate treating them as if they were harmless with respect to carcinogenic potential. Several employers, for instance insist that such substances must be treated with "care" or "respect," while also insisting that they call for significantly less protection than those substances known to be human carcinogens.

We think it improper to afford less protection to workers when exposed to substances found to be carcinogenic only in experimental animals. Once the carcinogenicity of a substance has been demonstrated in animal experiments, the practical regulatory alternatives are to consider them either non-carcinogenic or

carcinogenic to humans, until evidence to the contrary is produced. The first alternative would logically require, not relaxed controls on exposure, but exclusion from regulation. The other alternative logically leads to the treatment of a substance as if it was known to be carcinogenic in man.

We agree with the Director of NIOSH, and the report to the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General, U.S. Public Health Service, April 22, 1970, that the second alternative is the responsible and correct one. This decision accords with the work practices of some who object to the proposed regulation. For example, although the Pharmaceutical Manufacturers Association argues for the exclusion of research laboratories from the standard, it states as its ground the fact that employees in Pharmaceutical research are taught to work with all chemicals under the assumption that they are dangerous, unless it is specifically known that they are not.

(3) *The petition, zero tolerance, and permit system.* The petition of Oil, Chemical and Atomic Workers Union (OCAW) and Health Research Group (HRG) for an emergency temporary standard on ten substances proceeds on the assumption that any exposure to any amount of a carcinogenic substance must be prevented. Accordingly, it proposes a standard of zero tolerance permitting no exposure whatsoever. This objective would be accomplished by means of a permit system and frequent monitoring and reporting.

We agree with the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens that a safe level of human exposure to any of the 14 carcinogens cannot be established by application of present knowledge. But we are not prepared to

draw from this state of knowledge the conclusion that such levels do not exist. First, it is the professional opinion of many knowledgeable people that as yet undetermined safe levels of exposure possibly do exist. Also, a conclusion that safe levels do not exist seems questionable in view of other studies, some in the area of carcinogenicity which demonstrated that below a certain amount of a single or cumulative dosage, no detectable harm is caused, or if harm is caused, the extent of such harm will be of no practicable importance because the latency period prior to manifestation of harmful effects will be of greater duration than the normal lifespan of man. Secondly, no possible exposure to the carcinogens under any circumstances could only be guaranteed by a total ban on the manufacture, use (even for cancer research), and transportation of the substances. As long as the substances are used, exposure to some amounts may occur because of breakdown of equipment or human error. Accordingly, the intent of the standards is to reduce exposure of workers to any of the listed substances to the maximum extent practicable consistent with continued use.

Numerous objections have challenged the authority for, and the administrative feasibility of, the permit system proposed on July 16, 1973 (38 FR 18902). It is argued, for instance, that the Act requires the promulgation of general standards, in accordance with the procedures prescribed in section 6 of the Act, while the proposed permits would be tailored to particular users, and would be issued by a different procedure.

Another objection argues that a permit system, to be effective, would require authority to stop an operation involving a carcinogen by administrative action, in contravention of the statutory scheme which con-

templates judicial determinations resulting in the cessation of an operation.

With regard to feasibility, it is pointed out that a multitude of permits would be required, and that, therefore, the implementation of a permit system would require substantial resources and several years.

It has been made clear that there are numerous uses and processes involving carcinogens. It appears, for instance, that there are 800 to 1800 users of 4,4'-methylene bis(2-chloroaniline) alone. The investigations and evaluations of thousands of work situations involving a carcinogen, and the completion of the procedures, possibly including hearings, for the granting of the permits, would require many years and the diversion of substantial resources, even if available, from other serious occupational safety and health problems.

After considering the administrative and legal aspects of a permit system, as against those of general standards enforced by the use of the current enforcement tools of the Act, the decision has been made not to adopt a permit system.

The requirement in the adopted standards for employers to report the uses of carcinogens and the nature of operations involved, together with incidents of releases of carcinogens, will permit significant administrative surveillance.

(4) *Mixtures.* The proposal for this rulemaking proceeding, like the Emergency Temporary Standard, excludes from the scope of the standard mixtures containing less than specified percentages of the 14 listed substances. The specific figure as a cutoff point derives from the regulations of the Commonwealth of Pennsylvania and England, which also regulate exposure to carcinogens, and apparently have faced

the same administrative difficulties confronting OSHA. It is recognized that some of the carcinogens may be used in minute amounts with other substances, or may appear as unintended, undesired byproducts or contaminants of processes. Some of the substances are used in minute amounts in cancer research laboratories, and for medical purposes. The College of American Pathologists, for instance, points out that for years pathology laboratories and physicians have used benzidine and/or benzidine dihydrochloride for diagnostic purposes. The American Home Products Corporation calls attention to the use of beta-Propiolactone for the sterilization of vaccines and tissue grafts. Koppers, Inc., requests an exemption in some form for materials, such as coal tar and coal tar products, that contain trace amounts of some carcinogens as by-products or contamination of processes essential to our industrial society. It states that the application of the proposed standard to crude mixtures, such as coal tar and coal tar products, without any exemption, would have the effect of closing down large segments of industry, such as steelmaking, wood preserving, roofing, aluminum reduction, and possibly even power plants.

The adopted standards retain the proposed exclusion of solid or liquid mixtures containing less than 1 percent, by weight or volume, of eight of the carcinogens. Solid or liquid mixtures containing 4-Aminodiphenyl, Benzidine (and its salts), 4-Nitrobiphenyl, beta-Naphthylamine, bis-Chloromethyl ether and Methyl chloromethyl ether are excluded only if they contain less than 0.1 percent of those substances. Finally, an exclusion is provided in the destructive distillation of carbonaceous materials, for alpha-Naphthylamine and beta-Naphthylamine, which may occur in such processes.

The overall purpose of all the exclusions is to avoid substantial obstruction, if not stoppage, of the use of

many processes and products which are considered useful in industy and even in cancer research, and about which the record contains very little information. We do not know how many such products and processes there are, nor the availability of substitutes for all of the carcinogens involved, nor the effect of the other components of a mixture on the carcinogenic potentiality of the small amounts of the carcinogen involved. The exclusionary percentage for mixtures containing 4-Aminodiphenyl, Benzidine, 4-Nitrobiphenyl, beta-Naphthylamine, bis-Chloromethyl ether and Methyl chloromethyl ether has been lowered from 1 percent to 0.1 percent because these substances are known to be potent human carcinogens.

The exclusion for the destructive distillation of carbonaceous materials is for the purpose of avoiding the extreme consequences to the segments of the industry using vigorous thermal processes at a time when a separate standard-setting proceeding on coke oven emissions will afford the opportunity for a more in-depth consideration of this whole area (see 38 FR 26207). The exclusion of the mixtures rests, not on a finding that the mixtures are non-carcinogenic, but rather on a decision not to regulate them at this time, on the basis of the record of this proceeding.

(5) *Number of Standards Needed.* Another objection to the proposals is that the standard "lumps together" many different substances with different chemicals and physical properties, different physical states, different biological properties and different uses. There is merit in this objection. Accordingly, 14 standards are adopted, one for each substance listed in the proposal of July 16, 1973.

These standards recognize and provide for different uses and operations involving the regulated carcinogens. Ethyleneimine and beta-Propiolactone are

immediately corrosive, and provisions are made in the standards for these materials for deluge showers and eye wash fountains, located near places where exposures might be expected. Principally volatile materials will not be present long enough for routine washing or showering to have effect as a protective measure. Thus, a requirement to wash on each exit, and shower at the end of the day, would not offer any significant protection to employees working in areas where the volatile materials, Methyl chloromethyl ether, bis-Chloromethyl ether, Ethyleneimine and beta-Propiolactone, are present in a closed system or closed system transfer operation. Trace amounts that might be adsorbed onto exposed skin vaporize long before the employee would routinely wash or shower. Wash requirements are retained for these materials in isolated system operations because the closed confinement of glovebox gloves would inhibit vaporization if a leak should occur.

Special provisions are made for premix operations involving 4,4 Methylene-bis (2-chloroaniline) and liquid prepolymer. These premix solutions, frozen or otherwise, are packaged in such a manner and used only after the 4,4′-Methylene-bis(2-chloroaniline) and the prepolymer have started to react. No dust hazard exists and a vapor hazard is unlikely. For this reason, the standard requires only protective clothing such as smocks, coveralls, or long-sleeved shirts and pants, and gloves. This, we believe, will afford adequate protection for these workers.

On the other hand, some of the differences pointed out do not require different treatment. There are basically two strategies of control, regardless of the physical state of a carcinogen. One is to isolate the carcinogen and the other is to isolate the areas of possible exposure. In cases of isolated systems, the

physical state of the carcinogen may be disregarded for practical purposes. When a system is isolated and fully closed so that the substances cannot escape into the work environment, it does not matter if the substance in it is a solid, liquid, or gas. An isolated system achieved by engineering controls is the preferred approach and the basic approach adopted in the standards. That is, the preferred method of control is engineering control, such as by closed systems, mechanical seals, remote controls, and local exhaust ventilation. This approach most effectively isolates employees from potential contamination.

This is the reason for the ban on open vessel operations. Because of consideration of feasibility, special provisions are made for laboratory hoods and transfer point operations, and additional work practice requirements are made applicable to them.

When protection is afforded by means of personal protective equipment, it is thought best to require body coverage, regardless of the physical state of the substance and its path of travel into the body. The reason for such personal protection is that even if a substance is considered to do harm only when ingested or inhaled, it is prudent to provide protective garments to be discarded after use, so that a worker may not accidentally inhale or ingest contaminants adhering to his clothing or body. This precaution is reasonable, especially since the standards do not require full impervious air-supplied suits. OSHA agrees with the many comments that a full impervious air-supplied suit is cumbersome, while impervious garments with air-supplied hoods are adequate and more comfortable to the workers when used in accordance with the work practice provisions of these standards.

(6) *Research laboratories.* Numerous objections have been made to the proposal for identical treatment of

industrial use and laboratory use of the carcinogens. There are essentially three objections: (a) That laboratories use very small amounts of the substances; (b) that work is done by, or under the direction of, highly trained personnel; and (c) that, in the absence of an exemption or other special consideration, the standard as proposed would obstruct, and possibly even prevent much research including cancer research.

These objections are well-taken and special provisions are made applicable to laboratory activities. The provisions are derived from the Minimum Safety Guidelines for Research in Cancer (Part 1, For Research Involving Chemical Carcinogens), prepared in draft form by the Cancer Research Safety Committee of the National Cancer Institute. In addition, it is to be noted that the exclusion provisions for certain mixtures may, by themselves, make a whole standard inapplicable.

Personnel engaged in animal support activities must necessarily handle animals exposed in connection with experiments involving one or more of the carcinogens. Such support activities include the feeding of animals, cleaning of cages and the animal room, and caring for the animals, including weighing operations. Such close animal contact involves potential exposure both to a carcinogen and to metabolites of the carcinogen and therefore requires the more stringent controls for such personnel provided in the standards.

(7) *Signs and labels.* The controversy with regard to signs and labels centers on whether the word "cancer" should be used. We believe that a diluted form of warning will not suffice. We appreciate the concern of employers with the reactions of their employees and the users of their products. But we consider of paramount importance that a worker should be fully apprised and realize the possible risks in-

volved in his occupation. The use of the word "suspect" in the phrase "Cancer-Suspect" follows the revised Emergency Temporary Standard issued July 27, 1973. Coupled with the information and training requirement in the standard, it appears to provide the necessary warning to employees.

(8) *Information and training.* Employers are responsible for providing indoctrination and training to their employees on the nature of the carcinogenic hazards in the establishment, and the precautions to be used when working with or in the presence of the carcinogens. Information on the training and education to be provided to employees is specified in each of the standards for a carcinogenic agent.

(9) *Monitoring.* No provisions for specific techniques or instruments for environmental monitoring are contained in the standards adopted. OSHA has requested NIOSH to develop, on a priority basis, methods for determining qualitative and quantitative amounts of the carcinogens in the workplace.

(10) *Medical surveillance.* Medical surveillance by a physician is required in the standards prior to assignment, at yearly intervals thereafter and whenever known or possible exposure to a carcinogen has occurred. Medical surveillance is considered necessary because of the long latency period inherent in occupational carcinogenesis, since initiation of exposure and induction of cancer are not synchronous events.

(11) *Reports and records.* The standards require reports concerning the use of carcinogens, the number of employees in regulated areas, and incidents resulting in the release of a carcinogen in an area where employees may be potentially exposed. The standards also require records of medical examinations of employees. The reports and records are considered

necessary in order to monitor the effectiveness of the standards in protecting employees against occupational cancer and in order to obtain information, on a continuing basis, concerning the hazards found in the use of the carcinogens.

Accordingly, upon consideration of the whole record of this proceeding, 29 CFR Part 1910 is amended by revising § 1910.93c and by adding new §§ 1910.93d through 1910.93p, reading as follows:

§ 1910.93*l* *Ethyleneimine.*

(a) *Scope and application.* (1) This section applies to any area in which Ethyleneimine, Chemical Abstracts Service Registry Number 151564 is manufactured, processed, repackaged, released, handled, or stored, but shall not apply to transshipment in sealed containers, except for the labeling requirements under paragraphs (e)(2), (3), and (4) of this section.

(2) This section shall not apply to solid or liquid mixtures containing less than 1.0 percent by weight or volume of Ethyleneimine.

(b) *Definitions.* For the purposes of this section: (1) "Absolute filter" is one capable of retaining 99.97 percent of a mono disperse aerosol of 0.3 μm particles.

(2) "Authorized employee" means an employee whose duties require him to be in the regulated area and who has been specifically assigned by the employer.

(3) "Clean change room" means a room where employees put on clean clothing and/or protective equipment in an environment free of Ethyleneimine. The clean change room shall be contiguous to and have an entry from a shower room, where the shower room facilities are otherwise required in this section.

(4) "Closed system" means an operation involving Ethyleneimine where containment prevents the release

of Ethyleneimine into regulated areas, non-regulated areas, or the external environment.

(5) "Decontamination" means the inactivation of Ethyleneimine or its safe disposal.

(6) "Director" means the Director, National Institute for Occupational Safety and Health, or any person directed by him or the Secretary of Health, Education, and Welfare to act for the Director.

(7) "Disposal" means the safe removal of Ethyleneimine from the work environment.

(8) "Emergency" means an unforeseen circumstance or set of circumstances resulting in the release of Ethyleneimine which may result in exposure to or contact with Ethyleneimine.

(9) "External environment" means any environment external to regulated and nonregulated areas.

(10) "Isolated system" means a fully enclosed structure other than the vessel of containment of Ethyleneimine, which is impervious to the passage of Ethyleneimine, and which would prevent the entry of Ethyleneimine into regulated areas, nonregulated areas, or the external environment, should leakage or spillage from the vessel of containment occur.

(11) "Laboratory type hood" is a device enclosed on three sides and the top and bottom, designed and maintained so as to draw air inward at an average linear face velocity of 150 feet per minute with a minimum of 125 feet per minute; designed, constructed, and maintained in such a way that an operation involving Ethyleneimine within the hood does not require the insertion of any portion of any employees' body other than his hands and arms.

(12) "Nonregulated area" means any area under the control of the employer where entry and exit is neither restricted nor controlled.

(13) "Open-vessel system" means an operation involving Ethyleneimine in an open vessel, which is not in an isolated system, a laboratory type hood, nor in any other system affording equivalent protection against the entry of Ethyleneimine into regulated areas, nonregulated areas, or the external environment.

(14) "Protective clothing" means clothing designed to protect an employee against contact with or exposure to Ethyleneimine.

(15) "Regulated area" means an area where entry and exit is restricted and controlled.

(c) *Requirements for areas containing Ethyleneimine.* A regulated area shall be established by an employer where Ethyleneimine is manufactured, processed, used, repackaged, released, handled or stored. All such areas shall be controlled in accordance with the requirements for the following category or categories describing the operation involved: (1) *Isolated systems.* Employees working with Ethyleneimine within an isolated system, such as a "glove box" shall wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.

(2) *Closed system operation.* Within regulated areas where Ethyleneimine is stored in sealed containers or contained in a closed system, including piping systems, with any sample ports or openings closed while Ethyleneimine is contained within: Access shall be retricted to authorized employees only.

(3) *Open vessel system operations.* Open vessel system operations as defined in paragraph (b) (13) of this section are prohibited.

(4) *Transfer from a closed system, charging or discharging point operations, or otherwise opening a*

closed system. In operations involving "laboratory type hoods," or in locations where Ethyleneimine is contained in an otherwise "closed system," but is transferred, charged, or discharged into other normally closed containers, the provisions of this subparagraph shall apply. (i) Access shall be restricted to authorized employees only;

(ii) Each operation shall be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated. Clean makeup air shall be introduced in sufficient volume to maintain the correct operation of the local exhaust system.

(iii) Employees shall be provided with, and required to wear, clean, full body protective clothing (smocks, coveralls, or long-sleeved shirt and pants), and gloves prior to entering the regulated area.

(iv) Employees engaged in Ethyleneimine handling operations shall be provided with and required to wear and use a fullface, supplied air respirator, of the continuous flow or pressure-demand type, in accordance with § 1910.134.

(v) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified, as required under paragraphs (e)(2), (3), and (4) of this section.

(vi) Drinking fountains are prohibited in the regulated area.

(5) *Maintenance and decontamination activities.* In cleanup of leaks or spills, maintenance or repair operations on contaminated systems or equipment, where direct contact with Ethyleneimine could result, each authorized employee entering that area shall: (i) Be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood in accordance with § 1910.134.

(ii) Be decontaminated before removing the protective garments and hood;

(iii) Be required to shower upon removing the protective garments and hood.

(6) *Laboratory activities.* The requirements of this subparagraph shall apply to research and quality control activities involving the use of Ethyleneimine. (i) Mechanical pipetting aids shall be used for all pipetting procedures.

(ii) Experiments, procedures and equipment which could produce aerosols shall be confined to laboratory-type hoods or glove boxes.

(iii) Surfaces on which Ethyleneimine is handled shall be protected from contamination.

(iv) Contaminated wastes and animal carcasses shall be collected in impervious containers which are closed and decontaminated prior to removal from the work area. Such wastes and carcasses shall be incinerated in such a manner that no carcinogenic products are released.

(v) All other forms of Ethyleneimine shall be inactivated prior to disposal.

(vi) Laboratory vacuum systems shall be protected with high-efficiency scrubbers.

(vii) Employees engaged in animal support activities shall be *(a)* provided with, and required to wear, a complete protective clothing change, clean each day, including coveralls or pants and shirt, foot covers, head covers, gloves, and appropriate respiratory protective equipment or devices; and

(b) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The contents of such impervious containers shall be identified as required under paragraphs (e)(2), (3), and (4) of this section.

(c) Required to shower after the last exit of the day.

(viii) Employees, other than those engaged only in animal support activities, each day shall be *(a)* provided with and required to wear a clean change of appropriate laboratory clothing, such as a solid front gown, surgical scrub suit, or fully buttoned laboratory coat.

(b) Prior to each exit from a regulated area, employees shall be required to remove and leave protective clothing and equipment at the point of exit and at the last exit of the day, to place used clothing and equipment in impervious containers at the point of exit for purposes of decontamination or disposal. The containers shall be identified as required under paragraphs (e)(2), (3), and (4) of this section.

(c) Required to wash hands, forearms, face and neck upon each exit from the regulated area close to the point of exit, and before engaging in other activities.

(ix) Air pressure in laboratory areas and animal rooms where Ethyleneimine is handled and bioassay

studies are performed shall be negative in relation to the pressure in surrounding areas. Exhaust air shall not be discharged to regulated areas, nonregulated areas or the external environment unless decontaminated.

(x) There shall be no connection between regulated areas and any other areas through the ventilation system.

(xi) A current inventory of Ethylenemine shall be maintained.

(xii) Ventilated apparatus, such as laboratory type hoods, shall be tested at least semi-annually or immediately after ventilation modification or maintenance operations, by personnel fully qualified to certify correct containment and operation.

(d) *General regulated area requirements*—(1) *Employee identification.* A daily roster of employees entering regulated areas shall be established and maintained. The rosters or a summary of the rosters, shall be retained for a period of 20 years. The rosters and/or summaries shall be provided upon request to authorized representatives of the Assistant Secretary and the Director. In the event that the employer ceases business without a successor, rosters shall be forwarded by registered mail to the Director.

(2) *Emergencies.* In an emergency, immediate measures including, but not limited to, the requirements of subdivisions (i), (ii), (iii), (iv), and (v) of this subparagraph shall be implemented. (i) The potentially affected area shall be evacuated as soon as the emergency has been determined.

(ii) Hazardous conditions created by the emergency shall be eliminated and the potentially affected area shall be decontaminated prior to the resumption of normal operations.

(iii) Special medical surveillance by a physician shall be instituted within 24 hours for employees present in the potentially affected area at the time of the emergency. A report of the medical surveillance and any treatment shall be included in the incident report, in accordance with paragraph (f)(2) of this section.

(iv) Where an employee has a known contact with Ethyleneimine, such employee shall be required to shower as soon as possible, unless contraindicated by physical injuries.

(v) An incident report on the emergency shall be reported as provided in paragraph (f)(2) of this section.

(vi) Emergency deluge showers and eyewash fountains supplied with running potable water shall be located near, within sight of, and on the same level with locations where a direct exposure of Ethyleneimine would be most likely as a result of equipment failure, or improper work practice.

(3) *Hygiene facilities and practices.* (i) Storage or consumption of food, storage or use of containers of beverages, storage or application of cosmetics, smoking, storage of smoking materials, tobacco products or other products for chewing, or the chewing of such products, are prohibited in regulated areas.

(ii) Where employees wear protective clothing and equipment clean change rooms shall be provided, in accordance with § 1910.141(e), for the number of such employees required to change clothes.

(iii) Where toilets are in regulated areas, such toilets shall be in a separate room.

(iv) Where employees are required by this section to wash, washing facilities shall be provided in accordance with § 1910.141(d)(1) and (2)(ii) through (vii).

(v) Where employees are required by this section to shower, shower facilities shall be provided in accordance with § 1910.141(d)(3).

(4) *Contamination control.* (i) Regulated areas, except for outdoor systems, shall be maintained under pressure negative with respect to nonregulated areas. Local exhaust ventilation may be used to satisfy this requirement. Clean makeup air in equal volume shall replace air removed.

(ii) Any equipment, material, or other item taken into or removed from a regulated area shall be done so in a manner that does not cause contamination in nonregulated areas or the external environment.

(iii) Decontamination procedures shall be established and implemented to remove Ethyleneimine from the surfaces of materials, equipment and the decontamination facility.

(e) *Signs, information and training*—(1) *Signs.* (i) Entrances to regulated areas shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT
AUTHORIZED PERSONNEL ONLY

(ii) Entrances to regulated areas containing operations covered in paragraph (c)(5) of this section shall be posted with signs bearing the legend:

CANCER-SUSPECT AGENT EXPOSED IN THIS AREA IMPERVIOUS SUIT INCLUDING GLOVES, BOOTS, AND AIR-SUPPLIED HOOD REQUIRED AT ALL TIMES, AUTHORIZED PERSONNEL ONLY

(iii) Appropriate signs and instructions shall be posted at the entrance to, and exit from, regulated areas, informing employees of the procedures that must be followed in entering and leaving a regulated area.

(2) *Container contents identification.* (1) Containers of Ethyleneimine and containers required under

paragraphs (c)(4)(v) and (c)(6)(vii) (*b*), and (c) (6) (viii)(*b*) of this section which are accessible only to, and handled only by, authorized employees, or by other employees trained in accordance with subparagraph (5) of this paragraph, may have contents identification limited to a generic or proprietary name, or other proprietary identification, of the carcinogen and percent.

(ii) Containers of Ethyleneimine and containers required under paragraphs (c)(4)(v), (c)(6)(vii)(*b*), and (c)(6)(viii)(*b*) of this section which are accessible to, or handled by employees other than authorized employees or employees trained in accordance with subparagraph 5 of this paragraph shall have contents identification which includes the full chemical name and Chemical Abstracts Service Registry number as listed in paragraph (a)(1) of this section.

(iii) Containers shall have the warning words "CANCER-SUSPECT AGENT" displayed immediately under or adjacent to the contents identification.

(iv) Containers which have Ethyleneimine contents with corrosive or irritating properties shall have label statements warning of such hazards, noting, if appropriate, particularly sensitive or affected portions of the body.

(3) *Lettering.* Lettering on signs and instructions required by subparagraph (1) of this paragraph shall be a minimum letter height of 2 inches. Labels on containers required under this section shall not be less than ½ the size of the largest lettering on the package, and not less than 8 point type in any instance: *Provided,* That no such required lettering need be more than 1 inch in height.

(4) *Prohibited statements.* No statement shall appear on or near any required sign, label, or instruction which contradicts or detracts from the effect of any required warning, information or instruction.

(5) *Training and indoctrination.* (i) Each employee prior to being authorized to enter a regulated area, shall receive a training and indoctrination program including, but not necessarily limited to: *(a)* The nature of the carcinogenic hazards of Ethyleneimine, including local and systemic toxicity;

(b) The specific nature of the operation involving Ethyleneimine which could result in exposure;

(c) The purpose for and application of the medical surveillance program, including as appropriate, methods of self-examination;

(d) The purpose for and application of decontamination practices and purposes;

(e) The purpose for and significance of emergency practices and procedures;

(f) The employee's specific role in emergency procedures;

(g) Specific information to aid the employee in recognition and evaluation of conditions and situations which may result in the release of Ethyleneimine;

(h) The purpose for and application of specific first aid procedures and practices;

(i) A review of this section at the employee's first training and indoctrination program and annually thereafter.

(ii) Specific emergency procedures shall be prescribed, and posted, and employees shall be familiarized with their terms, and rehearsed in their application.

(iii) All materials relating to the program shall be provided upon request to authorized representatives of the Assistant Secretary and the Director.

(f) *Reports*—(1) *Operations.* Not later than March 1, 1974, the information required in subdivisions (i), (ii), (iii), and (iv) of this subparagraph shall be reported in writing to the nearest OSHA Area Director. Any changes in such information shall be similarly reported in writing within 15 calendar days of such change. (i) A brief description and in-plant location of the area(s) regulated and the address of each regulated area;

(ii) The name(s) and other identifying information as to the presence of Ethyleneimine in each regulated area;

(iii) The number of employees in each regulated area, during normal operations including maintenance activities and

(iv) The manner in which Ethyleneimine is present in each regulated area; e.g. whether it is manufactured, processed, used, repackaged, released, stored, or otherwise handled.

(2) *Incidents.* Incidents which result in the release of Ethyleneimine into any area where employees may be potentially exposed shall be reported in accordance with this subparagraph. (i) A report of the occurrence of the incident and the facts obtainable at that time including a report on any medical treatment of affected employees shall be made within 24 hours to the nearest OSHA Area Director.

(ii) A written report shall be filed with the nearest OSHA Area Director within 15 calendar days therafter and shall include: *(a)* A specification of the amount of material released, the amount of time involved, and an explanation of the procedure used in determining this figure;

(b) A description of the area involved, and the extent of known and possible employee exposure and area contamination, and

(c) A report of any medical treatment of affected employees, and any medical surveillance program implemented; and

(d) An analysis of the circumstances of the incident, and measures taken or to be taken, with specific completion dates, to avoid further similar releases.

(g) ***Medical surveillance.*** At no cost to the employee, a program of medical surveillance shall be established and implemented for employees considered for assignment to enter regulated areas, and for authorized employees. (1) ***Examination.*** (i) Before an employee is assigned to enter a regulated area, a preassignment physical examination by a physician shall be provided. The examination shall include the personal history of the employee, family and occupational background, including genetic and environmental factors.

(ii) Authorized employees shall be provided periodic physical examinations, not less often than annually, following the preassignment examination.

(iii) In all physical examinations, the examining physician shall consider whether there exist conditions of increased risk, including reduced immunological competence, those undergoing treatment with steroids or cytotoxic agents, pregnancy and cigarette smoking.

(2) *Records.* (1) Employers of employees examined pursuant to this paragraph shall cause to be maintained complete and accurate records of all such medical examinations. Records shall be maintained for the duration of the employee's employment. Upon termination of the employee's employment, including retirement or death, or in the event that the employer ceases business without a successor, records, or notarized true copies thereof, shall be forwarded by registered mail to the Director.

(ii) Records required by this paragraph shall be provided upon request to authorized representatives of the Assistant Secretary or the Director; and upon request of an employee or former employee, to a physician designated by the employee or to a new employer.

(iii) Any physician who conducts a medical examination required by this paragraph shall furnish to the employer a statement of the employee's suitability for employment in the specific exposure.

• • • • • • • • •

APPENDIX C

STATUTE INVOLVED

Occupational Safety and Health Act
of 1970, 29 U.S.C. §655(b)

* * *

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

* * *

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate,

such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of title 5, United States Code, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

* * *

APPENDIX D

UNITED STATES COURT OF APPEALS FOR FOR THE THIRD CIRCUIT

No. 74-1129
No. 74-1149
No. 74-1268

SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, *et al.*,

Petitioners in No. 74-1129

v.

PETER J. BRENNAN, Secretary, Department of Labor, and JOHN H. STENDER, Assistant Secretary of Labor for Occupational Safety and Health,

Respondents

OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO and HEALTH RESEARCH GROUP,

Petitioners in No. 74-1149

v.

PETER J. BRENNAN, Secretary United States Department of Labor, *et al.*,

Respondents

POLYURETHANE MANUFACTURERS ASSOCIATION,

Petitioner in No. 74-1268

v.

DEPARTMENT OF LABOR, PETER J. BRENNAN, Secretary Department of Labor, etc., *et al.*,

Respondents

ON PETITION FOR REVIEW OF ACTION OF THE ASSISTANT SECRETARY OF LABOR FOR OCCUPATIONAL SAFETY AND HEALTH

Present: HASTIE, GIBBONS and WEIS, *Circuit Judges*

JUDGMENT

These causes came on to be heard on the record from the Assistant Secretary of Labor for Occupational Safety and Health, and were argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the proceedings be, and the same are hereby remanded insofar as the standards relating to medical examinations, applicable to all chemicals, are concerned; and it is further here ordered and adjudged by the Court that the regulations applicable to 4,4' methylene bis (2-chloroaniline) (MOCA) be, and the same are hereby vacated, and the cause be, and the same is hereby remanded for the publication of a proposed standard, to be followed by the required procedures for allowance of comments and hearing; and it is further here ordered and adjudged by this Court that to the extent that the standards in question relate to research laboratories, the said standards be, and the same are hereby vacated, and the cause be, and the same is hereby remanded to OSHA for further proceedings, all in accordance with the opinion of this Court.

ATTEST:

/s/ Thomas P. Quinn
Clerk

December 17, 1974

Supreme Court, U. S.
FILED
AUG 6 1975
MICHAEL RODAK, JR., CLERK

No. 74-1443

In the Supreme Court of the United States

OCTOBER TERM, 1975

OIL, CHEMICAL AND ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO, ET AL., PETITIONERS

v.

JOHN T. DUNLOP, SECRETARY, UNITED STATES DEPARTMENT OF LABOR, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MEMORANDUM FOR THE RESPONDENTS IN OPPOSITION

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In the Supreme Court of the United States

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v.

JOHN T. DUNLOP, SECRETARY, UNITED STATES DEPARTMENT OF LABOR, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MEMORANDUM FOR THE RESPONDENTS IN OPPOSITION

The petition seeks review of the judgment of the court of appeals affirming standards regulating worker exposure to mixtures containing more than specified percentages of fourteen chemical carcinogens (Pet. App. 1a-13a). Petitioners claim that the court of appeals employed improper criteria for review of the standards, and that the standards are deficient in that they do not impose an objective measure of exposure—whether at zero or some other level—for purposes of control, and do not require monitoring.

1. The standards were promulgated by the Secretary of Labor pursuant to Sections 6(b) and (c) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 655(b) and (c)[1], on

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[1]Sections 6(b)(5) and (7) of the Act, upon which petitioners' argument is based, are reprinted at Pet. App. 43a-44a.

January 29, 1974 (39 Fed. Reg. 3756-3797).[2] Their issuance was accompanied by a statement of reasons explaining the basis for the standards and the reasons underlying the policy choices made by the Secretary (Pet. App. 14a-42a).

The Secretary's determination that certain chemicals should be classified as carcinogens (that is, substances known to cause cancer) requiring regulation was based on the criterion that substances shown to cause cancer in two animal species are to be treated as posing an impermissible danger to man until evidence to the contrary is produced. Applying this criterion, the Secretary classified fourteen chemicals as carcinogens.[3]

Having classified substances as carcinogens, the Secretary then adopted "cut-off" levels for the purpose of determining the applicability of regulatory provisions. In the case of eight substances, solid or liquid mixtures containing less than one percent by weight or volume of the substance are excluded from regulation, while in the case of six substances, mixtures containing less than 0.1 percent are

---

[2]A temporary emergency standard issued pursuant to 29 U.S.C. 655(c) had earlier been vacated by the court of appeals for failure of the Secretary adequately to state his reasons for issuing the standard. *Dry Color Manufacturers' Association* v. *Department of Labor*, 486 F. 2d 98 (C.A. 3).

[3]The Secretary's classification of the chemical ethyleneimine (EI) as a carcinogen was sustained in *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F. 2d 1155 (C.A. 3), certiorari denied, No. 74-789 (March 17, 1975). The classification of all other challenged substances was sustained in the present case (Pet. App. 4a-5a), although the rule regulating one such substance was remanded for correction of defects in the rule-making proceedings (Pet. App. 5a-9a). The parties that challenged the classification of substances in the court of appeals in this case have not sought review in this Court.

excluded (Pet. App. 23a). In support of this mode of regulation the Secretary noted that state regulatory bodies had adopted similar cut-off levels, that those levels were intended to exclude from regulation only minute trace amounts of the regulated substances, and that blanket application of the standards' requirements might create "substantial obstruction * * * of the use of many processes and products * * * about which the record contains very little information" (Pet. App. 22a-24a).

The Secretary considered and rejected petitioners' submission concerning the need for a zero exposure standard[4] (Pet. App. 20a-21a):

> The petition of Oil, Chemical and Atomic Workers Union (OCAW) and Health Research Group (HRG) for an emergency temporary standard on ten substances proceeds on the assumption that any exposure to any amount of a carcinogenic substance must be prevented. Accordingly, it proposes a standard of zero tolerance permitting no exposure whatsoever. This objective would be accomplished by means of a permit system and frequent monitoring and reporting.
>
> We agree with the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens that a safe level of human exposure to any of the 14 carcinogens cannot be established by application of present knowledge. But we are not prepared to draw from this state of knowledge the conclusion that such levels do not exist. First, it is the professional opinion of many knowledgeable

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[4]The zero exposure standard proposed by petitioners related to atmospheric concentration. This standard differs from the cut-off levels adopted by the Secretary, which, as shown above, relate to concentration in solid or liquid mixtures.

people that as yet undetermined safe levels of exposure possibly do exist. Also, a conclusion that safe levels do not exist seems questionable in view of other studies, some in the area of carcinogenicity which demonstrated that below a certain amount of a single or cumulative dosage, no detectable harm is caused, or if harm is caused, the extent of such harm will be of no practicable importance because the latency period prior to manifestation of harmful effects will be of greater duration than the normal lifespan of man. Secondly, no possible exposure to the carcinogens under any circumstances could only be guaranteed by a total ban on the manufacture, use (even for cancer research), and transportation of the substances. As long as the substances are used, exposure to some amounts may occur because of breakdown of equipment or human error. Accordingly, the intent of the standards is to reduce exposure of workers to any of the listed substances to the maximum extent practicable consistent with continued use.

With regard to petitioners' request for monitoring, the Secretary explained that because adequate techniques for monitoring atmospheric concentrations of these substances were not available, he had requested the National Institute for Occupational Safety and Health "to develop, on a priority basis, methods for determining qualitative and quantitative amounts of the carcinogens in the workplace" (Pet. App. 28a).

The standards seek to assure employees who work with the regulated chemicals a safe working environment, by prohibiting the use of any of the substances in an open vessel, by requiring negative air pressure where such substances are used to insure that they cannot escape, by providing requirements for protective clothing to be

worn by workers who might be exposed to the chemical, by requiring warning signs and employee education programs, and by requiring medical surveillance of workers.

2. While petitioners assert that the standards are deficient in two specific respects (discussed, *infra*), they also contend that the court of appeals applied an incorrect standard of review in sustaining the Secretary's determinations. But every court of appeals that has reviewed regulations promulgated in informal rulemaking under the Act has recognized that to the extent the Secretary finds facts, they must be supported by substantial evidence; and to the extent that the Secretary exercises what is more akin to legislative judgment, his determination must be reasonable in light of the statutory policies he is charged with effectuating. See, *e.g.*, *Society of the Plastics Industry, Inc.* v. *Occupational Safety & Health Administration*, 509 F. 2d 1301 (C.A. 2), certiorari denied *sub nom. Firestone Plastics Co.* v. *Department of Labor*, No. 74-1185 (May 27, 1975); *Industrial Union Dep't, AFL-CIO* v. *Hodgson*, 499 F. 2d 467, 475-478 (C.A.D.C); *Nat'l Roofing Contractors Ass'n* v. *Brennan*, 495 F. 2d 1294, 1296-1299 (C.A. 7), certiorari denied, 419 U.S. 1105; *Florida Peach Growers Ass'n* v. *Department of Labor*, 489 F. 2d 120, 124, 128-132 (C.A. 5); *Associated Industries of New York State, Inc.* v. *Department of Labor*, 487 F. 2d 342, 352-354 (C.A. 2).

That is precisely the standard of review applied by the court of appeals in this case.[5] This Court has twice refused

---

[5]The court of appeals applied the same standard that it had employed in *Synthetic Organic Chemical Manufacturers Association, supra* (Pet. App. 9a-10a). In that case the court of appeals, stating (503 F. 2d at 1159) that its task was to "review for consistency between the Secretary's rule and the statutory language and purpose" and to "determine

to review a contention that this standard of review was improper. See *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F. 2d 1155 (C.A. 3), certiorari denied, No. 74-789 (March 17, 1975); *Society of the Plastics Industry, Inc.* v. *Occupational Safety & Health Administration, supra.*

3. Petitioners' contention that the Secretary violated Section 6(b)(5) by not setting "a performance standard, whether at the zero level or some other level" (Pet. 7-8) is based on the assumption that a performance standard is required in every case. But Section 6(b)(5) expressly requires that such performance levels be specified only "[w]henever practicable." Neither petitioners, nor any other party, nor the expert bodies which participated in this rulemaking were able to suggest a numerical exposure level because the requisite data was not available. In view of this record and Section 6(b)(5)'s mandate that standards

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if the Secretary applied the [correct statutory criteria]" (503 F.2d at 1160), held (*ibid.*):

> Judicial review of a §6 standard properly includes at least the following:
>
> (1) determining whether the Secretary's notice of proposed rule making adequately informed interested persons of the action taken;
>
> (2) determining whether the Secretary's promulgation adequately sets forth reasons for his action;
>
> (3) determining whether the statement of reasons reflects consideration of factors relevant under the statute;
>
> (4) determining whether presently available alternatives were at least considered; and
>
> (5) if the Secretary's determination is based in whole or in part on factual matters subject to evidentiary development, whether substantial evidence in the record as a whole supports the determination.

be "feasible,"[6] the court's affirmance of the Secretary's decision to adopt a middle ground by requiring stringent protection against all but trace amounts of these substances (Pet. App. 9a-10a) was both reasonable and correct. Cf. *Dry Color Manufacturers' Association* v. *Department of Labor*, 486 F. 2d 98, 108 and n. 18 (C.A. 3); *Industrial Union Dep't, AFL-CIO* v. *Hodgson, supra*, 499 F.2d at 474-479.

Moreover, the standards issued by the Secretary embody objective criteria that promote effective enforcement of the policies of the Act.

4. Finally, petitioners contend that the Secretary violated Section 6(b)(7)[7] by failing to impose a requirement that employers conduct atmospheric monitoring to determine airborne concentrations of these substances in their workplaces.

But in light of the Secretary's finding that numerical exposure limits could not be established, monitoring (even if technologically feasible) would be largely pointless.

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[6]Although petitioners now refer to a zero exposure "or some other level" (Pet. 8) in the rule-making proceedings and before the court of appeals, petitioners contended that a zero level was required. The Secretary rejected this contention, finding that it was not justified by the record and, moreover, could be achieved only by a total ban on use. As the court of appeals held, citing *Industrial Union Dep't, AFL-CIO* v. *Hodgson, supra*, 499 F. 2d at 478, "Congress does not appear to have intended to protect employees by putting their employers out of business * * * " (Pet. App. 10a).

[7]"Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures * * * and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." 29 U.S.C. 655(b)(7) (Pet. App. 43a-44a).

Moreover, the Secretary properly found that monitoring techniques that would reliably measure atmospheric concentration of carcinogens were not presently available (Pet. App. 28a).[8]

The Secretary has requested the National Institute for Occupational Safety and Health to develop monitoring techniques on a priority basis. Accordingly, the court of appeals held (Pet. App. 12a) that the Secretary has properly "deferred implementation of monitoring requirements pending further scientific development of methods for so doing."

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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AUGUST 1975.

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[8]Petitioners' reliance on the Secretary's asserted disregard for his "own compilation of available monitoring techniques" (Pet. 11 and n. 13) is misplaced. The document relied upon clearly indicated that reliable technology was largely unavailable. Moreover, petitioners were unable to cite any specific reliable monitoring techniques. 38 Fed. Reg. 4038.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-1443

OIL, CHEMICAL & ATOMIC WORKERS INTERNATIONAL UNION, AFL-CIO, ET AL., *Petitioners,*

v.

JOHN T. DUNLOP, ET AL., *Respondents.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR RESPONDENTS SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION ET AL., IN OPPOSITION

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v.

JOHN T. DUNLOP, ET AL., *Respondents.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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BRIEF FOR RESPONDENTS SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, ET AL., IN OPPOSITION

OPINIONS BELOW

The opinion of the Court of Appeals for the Third Circuit is reported at 506 F.2d 385. The opinion was issued in three consolidated cases (petitions for review) brought by three different groups of petitioners to review a set of regulations promulgated by the Assistant Secretary of Labor for Occupational Safety &

Health.[1] The Court of Appeals had issued an earlier opinion in a closely-related segment of one of these same three consolidated cases. This earlier opinion is reported at 503 F.2d 1155. The bifurcated nature of the proceedings in the Third Circuit came about after the three groups of petitioners and OSHA had joined together in a stipulation and motion to consolidate the cases. A Motion for Stay of the portion of the OSHA regulations pertaining to ethyleneimine ("EI") was made. During a hearing on the Motion for Stay, the Court of Appeals *sua sponte* ordered that the portion of the regulations subject to the stay motion be considered on an expedited basis and be severed from the rest of the consolidated cases. The expedited and severed portion of the cases was subject of the first opinion of the Court of Appeals. Thereafter, a petition for writ of certiorari was taken from the first opinion; the petition was denied by this Court on March 17, 1975.[2]

The rulemaking order promulgating the regulations (29 C.F.R. §§ 1910.93*c-p*) is found at 39 *Fed. Reg.* 3756 (January 29, 1974), and is also set out in Appendix B to the Petition filed in this case.

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[1] The Occupational Safety and Health Act, 29 U.S.C. §§ 651 *et seq.* is written in terms of a grant of authority to the Secretary of Labor. The Secretary has delegated his responsibilities under the Act to the Assistant Secretary of Labor for Occupational Safety & Health. For purposes of simplicity, this brief will henceforth use the terms "the Secretary" or "OSHA" to refer both to the authority granted by the Act and to the actual official who promulgated the regulations.

[2] *Synthetic Organic Chemical Mfrs. Ass'n* v. *Brennan,* No. 74-789. Concurrently with this Brief in Opposition, the SOCMA respondents are filing a conditional Petition for Rehearing of the Order Denying Certiorari in No. 74-789.

JURISDICTION

The jurisdictional requisites are adequately set out in the Petition.

QUESTIONS PRESENTED

1. Whether OSHA in promulgating similar occupational health regulations for each of fourteen chemicals said to be carcinogens or to have a carcinogenic "potential",[3] could rely largely on "work practice" requirements, in contrast to "performance" requirements.

2. Whether it was "appropriate" under the Act for OSHA to defer inclusion of provisions for monitoring in standards for particular chemicals pending technological development and identification of monitoring measures.

STATUTE INVOLVED

Petitioners have set out as Appendix C to their Petition paragraphs 6(b)(5) and 6(b)(7) of the Occupational Safety and Health Act of 1970 ("the Act"), 29 U.S.C. § 655(b)(5), (b)(7). Section 6 of the Act in its entirety seems pertinent to this Petition; Section 6 is set out as Appendix A to this Brief, *infra,* at 1a.

STATEMENT OF THE CASE

The regulations involved in the present Petition are "permanent" regulations promulgated under subsec-

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[3] OSHA based regulation of some of the chemicals such as ethyleneimine ("EI") upon a finding of "carcinogenic potential" (see Pet. Appx., at 18a), and not upon a finding of carcinogenicity in man. The validity of OSHA's finding of such a "potential" especially as tested against its own criterion for making such a finding, was addressed in the earlier portion of this case to reach this Court. *Synthetic Organic Chemical Mfrs. Ass'n* v. *Brennan,* No. 74-789, *cert. denied,* — U.S. —, 95 S. Ct. 1396 (1975).

tion 6(b) of the Act. These regulations were, however, preceded by so-called "emergency temporary standards" issued by OSHA under subsection 6(c) of the Act. The positions of the parties at this juncture can best be understood and assessed by a brief review of the entire chain of events leading to the decision of the Court of Appeals for which review is being sought. Petitioners have set out the regulation for EI (29 C.F.R. § 1910.93*l*) as an example of regulations issued for each of the fourteen chemicals and have made various references to EI in their Petition. Therefore, specific references will be made in the following statement to the steps taken respecting EI at various stages in the proceeding.

A. The Emergency Temporary Standard

OSHA began examining the prospective regulation of certain suspected occupational carcinogens as early as the first part of 1972.[4] In May, 1972, OSHA wrote to the National Institute of Occupational Safety and Health ("NIOSH") requesting "all available information of known carcinogens used in industry"—noting specifically nine chemicals not including EI—and requesting "your recommendations for handling these substances with regard to writing standards".

NIOSH, an agency in the Department of Health, Education and Welfare, created by the Act to provide scientific assistance to OSHA, did not respond that any emergency existed. Rather, it published in the *Federal Register* for July 6, 1972 (37 *Fed. Reg.* 13285), a notice that it wished to develop "criteria documents" (a

[4] The background of the promulgation of the EI standard was reviewed by OSHA in the preamble to the permanent standard, at 39 *Fed. Reg.* 3756 (Jan. 29, 1974) (see Pet. Appx. at 14a-16a).

normal step in the formulation of permanent standards) on fifteen chemicals, including EI. NIOSH said it believed these chemicals were "known or suspected carcinogenic substances", and that it would welcome information on these substances within the following ninety days.

On December 29, 1972, the Health Research Group and the Oil, Chemical & Atomic Workers International Union ("HRG-OCAW"), with considerable publicity, petitioned OSHA to issue a single emergency temporary standard covering ten of the fifteen chemicals mentioned by NIOSH's July 6, 1972, notice in the *Federal Register*. The HRG-OCAW petition proposed a standard of a sort, *i.e.*, it "propose[d] a standard of zero tolerance permitting no exposure whatsoever". Pet. Appx. at 20a. It did not include EI within the group of ten chemicals to be subject to the broad zero tolerance standard. On February 9, 1973, OSHA published in the *Federal Register* notice of the filing of the HRG-OCAW petition, along with the standard proposed in their petition. OSHA invited public comment by March 11, 1973, on the petition and on the ten chemicals named in it (38 *Fed. Reg.* 4037).

On April 17, 1973, HRG-OCAW brought a well-publicized suit to compel OSHA to issue an emergency temporary standard for the ten chemicals (not including EI) listed in the petition filed with OSHA. *Oil, Chemical & Atomic Workers International Union* v. *Brennan,* Civil Action No. 730-73 (D.D.C., filed April 17, 1973). Shortly thereafter, OSHA did issue an emergency standard, dated April 26, 1973, and published May 3, 1973, at 38 *Fed. Reg.* 10929. The OSHA emergency standard covered fourteen chemicals, including four chemicals, among them EI, which were not

mentioned in the HRG-OCAW petition. The emergency standard imposed a set of uniform requirements, applicable alike to each of the listed chemicals. Thus, it adopted the format of the HRG-OCAW petition, but it did not adopt the zero-tolerance standard set out in the petition.

Thereafter, Petitions for Review of the emergency temporary standard were filed in the United States Court of Appeals for the Third Circuit by interested chemical industry trade associations and a number of individual chemical companies, and by HRG-OCAW. In *Dry Color Mfrs.' Ass'n* v. *Department of Labor,* 486 F.2d 98 (3d Cir. 1973), the Third Circuit vacated the emergency temporary standard as to EI and as to 3,3'-dichlorobenzidine ("DCB") and remanded the proceedings to OSHA. The court held that the statement of reasons and findings of fact proffered by OSHA to support the emergency temporary standard were inadequate, and that it was adopting the remedy of vacating the standard "[i]n view of our considerable doubts as to whether there is sufficient evidence in the record to support the finding that DCB and EI are carcinogenic in man. . . ." (486 F.2d at 107 n.13.) HRG-OCAW had contended that the Court should require OSHA to incorporate a use-permit system which would achieve zero exposure. The court found it unnecessary to address this contention in light of its disposition of the case. (486 F.2d at 108 & n.18.)

B. Administrative Proceedings for the Permanent Standard

Section 6(c)(3) of the Act (29 U.S.C. § 655(c)(3)) requires OSHA to adopt a permanent standard within six months of issuance of an emergency temporary standard and provides that the temporary standard as published shall serve as a proposed rule for the rule-

making proceeding. OSHA had begun to take the procedural steps required to arrive at a permanent standard prior to the Third Circuit's decision of October 4, 1973, in the *Dry Color* case.

OSHA issued the emergency temporary standard as a proposed permanent standard. Written comments were invited. The rulemaking proceeding also involved the formation of an advisory committee which, as the Third Circuit subsequently said, "was instructed that only one set of standards would be promulgated for all fourteen chemicals, despite the substantial differences in their properties and their industrial and laboratory uses." (Pet. Appx. at 8a.) The advisory committee submitted its recommendation to OSHA, and these recommendations were published in the *Federal Register* on September 7, 1973. Public hearings were commenced immediately thereafter on September 11, 1973. (Pet. Appx. at 6a.)

On November 29, 1973, by which date permanent standards had not yet issued, HRG-OCAW again brought an action for a declaratory judgment and mandatory injunction against OSHA, alleging that it had wrongfully failed to issue a permanent standard or, alternatively, to revoke the emergency temporary standard, within six months as required by Section 6(c)(3) of the Act. *Oil, Chemical & Atomic Workers International Union* v. *Brennan,* Civil Action No. 2127-73 (D.D.C., filed November 29, 1973). HRG-OCAW thereafter filed a motion for summary judgment, which was set for hearing on January 29, 1974. On that date, permanent standards were published in the *Federal Register* for fourteen different chemicals, including EI, and the lawsuit was no longer prosecuted. The permanent standards took the form of separate stan-

dards for each chemical although as the Third Circuit noted "[m]uch of the language, however, in the separate standards is merely duplication of that governing all of the other chemicals". (Pet. Appx. at 8a.) The individual standards were also very similar in substance to the emergency standard.

After OSHA issued these permanent standards, three separate Petitions for Review were filed in the Court of Appeals for the Third Circuit—by the Synthetic Organic Chemical Manufacturers Association ("SOCMA") along with other interested trade associations and individual companies,[5] by HRG-OCAW, and by the Polyurethane Manufacturers Association ("PMA"). The petitioners in the Court of Appeals joined with OSHA to stipulate and move for consolidation of the actions. SOCMA then sought a stay of the EI standard. At the hearing on the stay motion, the Third Circuit panel *sua sponte* ordered that consideration of the EI standard be expedited and be severed from the rest of the consolidated cases. The Court then issued a stay of the EI standard pending its disposition on the merits.

C. The Decisions of the Court of Appeals

1. *The EI Decision*

In its first decision,[6] issued on August 26, 1974, the Third Circuit considered the validity of the OSHA

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[5] This group of petitioners in the Third Circuit will be collectively referred to in this brief as "SOCMA".

[6] *Synthetic Organic Chemical Mfrs. Ass'n* v. *Brennan*, 503 F.2d 1155 (3d Cir. 1974), *cert. denied*, — U.S. —, 95 S. Ct. 847 (1975).

standard for EI. SOCMA, HRG-OCAW, and OSHA had each filed briefs and participated in oral argument on this phase of the case. The decision to a large extent concerns itself with the scope of review mandated by subsection 6(f) of the Act, 29 U.S.C. § 655(f). That subsection requires that an OSHA standard be "supported by substantial evidence in the record considered as a whole". The Third Circuit admitted that "[i]t is clear that application of the substantial evidence test to informal rulemaking was a deliberate legislative compromise between the House and Senate versions of the bill which became law" (503 F.2d at 1158). Nonetheless, the court ruled that a narrower standard of review was appropriate for what it called "legislative policy decisions" by the Secretary. The court apparently was of the view that with respect to such "policy" decisions the statutory substantial evidence criterion is not applicable and held that it is sufficient for OSHA merely to demonstrate that it has considered the "factors relevant under the statute" and "presently available alternatives" before reaching a decision (503 F.2d at 1160).

Then, despite the factual nature of the questions posed respecting whether EI should be regulated as a carcinogen based on "potential", the court applied its very limited test of review for "policy" questions. It thus did not review the evidence in the record respecting any "potential", nor did it review the countervailing evidence in the record. In particular, it did not examine whether OSHA had followed its own stated criterion for assessing carcinogenic "potential", even assuming that the adoption of the criterion itself (which occurred in this administrative proceeding)

was a "policy" judgment. The court did vacate the special provisions in the EI standard for laboratories.[7]

2. *The Subsequent Decision*

Thereafter, the Third Circuit considered the remaining portions of the case. Two of the three judges of the Third Circuit who had heard the EI case were also on the panel of the court hearing the remaining issues. On December 17, 1974, the court rejected a challenge to OSHA's determination to regulate three of the other chemicals among the fourteen subject to the standards. However, the court vacated the standard for one of these chemicals, on the ground that OSHA had not complied with the statutorily-prescribed procedures for use of advisory committees and for publication of and opportunity for comment on proposed or recommended standards.[8]

The court then turned to the HRG-OCAW contentions. HRG-OCAW objected to "the Secretary's erroneous failure to order a performance standard allowing no detectable worker exposure" (Court of Appeals Brief for OCAW-HRG petitioners, at 21),

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[7] The court below vacated the laboratory standard for lack of notice: "We note that there was a lack of notice regarding OSHA's plans to make special provisons regarding EI's use in research laboratories. The Secretary's notice did not advise that the agency planned to make special provisions regarding EI use in laboratories. Because of this, we hold that to the extent that the standards in question relate to research laboratories, they will be vacated and remanded to OSHA." (503 F.2d at 1160.)

[8] The procedural objection was only raised by one petitioner, PMA, with regard to the one chemical, MOCA®. (Pet. Appx. at 5a.)

and recognized that the judgment of OSHA on such a matter would be judged against the test adopted earlier by the court for "policy" matters. (*Id.*) Understandably, the court below considered HRG-OCAW's claim in the zero exposure context, and held that OSHA's decision not to adopt a performance standard based upon zero exposure was "a reasonable exercise of [OSHA's] judgment in the policy-making sphere". (Pet. Appx. at 10a.)

OSHA had deferred imposition of monitoring requirements pending development and identification of analytical "techniques or instruments for environmental monitoring . . . ." (Pet. Appx. at 28a.) The court rejected a challenge to this deferral, remarking that it would not upset a "pragmatic" judgment by OSHA to seek prompt development of monitoring methods "on a priority basis . . . ." (Pet. Appx. at 11a-12a.)

HRG-OCAW had also objected to OSHA's having imposed general requirements for medical surveillance by a physician, contending that the regulations should "prescribe specific medical protocols and diagnostic tests to be given employees who work with the chemicals". (Pet. Appx. at 12a.) Here, the Third Circuit noted that the chemicals varied in their effect and while particular tests for specific chemicals seemed appropriate, OSHA had not called for further study or development. Accordingly, the court remanded each of the fourteen separate standards insofar as medical surveillance was concerned. (Pet. Appx. at 12a-13a.)

ARGUMENT

A. There Are Important Issues Deserving of this Court's Attention

The Occupational Safety and Health Act is a comprehensive piece of legislation with far-reaching impact on the nation's economy, on people's jobs, and on safety in the workplace. The Secretary of Labor's responsibilities in setting occupational safety and health standards are the cornerstone of this legislation, and as such proper promulgation of these standards and subsequent careful judicial review are of considerable importance to the nation.

This case involves a set of such regulations. As one might expect, these particular regulations in their own right have an impact on a substantial number of industrial operations, as well as governmental, research, and educational activities. Many more regulations of a similar nature can be expected in the future.[9] Accordingly, the issues posed by the Petition here and by the earlier Petition in No. 74-789 take on an added importance.

The bifurcated proceedings in the Third Circuit have served to sift out and to sharpen three legal questions respecting which disagreement among the parties still remains. Two of those questions are posed in this Petition. They are in over-simplified terms (1) whether OSHA was required by the Act to frame the regulations in terms of a "performance" requirement or standard and not a "work practice" standard, and (2) whether it was "appropriate" under the Act for OSHA to defer

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[9] OSHA has announced plans to set standards for 386 chemicals in 23 chemical groups, with regulations similar to those at issue here, over the next two years. 4 Occup. Safety & Health Rep. 732, 752-59 (Nov. 21, 1974). The Petition at pages 20-21 also describes OSHA's planned rulemaking efforts for other chemicals.

inclusion of provisions for monitoring in standards for particular chemicals pending technological development and identification of monitoring measures. The third question was presented by the Petition in No. 74-789 which this Court denied on March 17, 1975, *i.e.*, (3) whether the Act's provisions for judicial review under the substantial evidence test should be construed as restricting review of "policy" issues, including such factual issues as whether OSHA correctly applied its own criterion for determining carcinogenic "potential". Each of these legal issues necessarily is presented on the factual base provided by the administrative proceedings. However, these legal issues do not depend for their resolution upon technical determinations, so they would not involve the Court in complex scientific matters.

The SOCMA respondents suggest that this Court should either grant petitions for writs of certiorari to hear all three issues, or it should hear none of them. Because of the Third Circuit's bifurcation of issues in the consolidated cases, this Court has already been presented with the scope-of-judicial-review issue in the prior Petition (No. 74-789). To enable the Court to consider together each of the three aforementioned interrelated issues, with this Brief in Opposition to the present Petition the SOCMA respondents have filed concurrently a Petition for Rehearing of the Order Denying Certiorari in No. 74-789.

B. HRG-OCAW Improperly Seek To Frame In the Abstract Questions Respecting Whether the OSHA Regulations Are Appropriate "Performance" Standards Under the Act

The HRG-OCAW petitioners would present this Court with the abstract question of whether OSHA improperly adopted for each of the fourteen chemicals

being regulated a standard based largely on "work practices" as contrasted to a "performance" standard. The HRG-OCAW petitioners say that "section 6(b)(5) and 6(b)(7) [of the Act] *required* a performance standard, monitoring, and medical surveillance, as well as appropriate protective equipment, labels, and warnings". (Petition, at 14 (emphasis added).) HRG-OCAW say the Third Circuit refused to focus on this abstract performance-standard requirement, viewing instead, and mistakenly, the question before it as whether a particular performance standard (zero exposure) was required.

There are three insurmountable difficulties with the present HRG-OCAW position. First, the present standard is in fact a "performance standard"; there is nothing in the Act to indicate that a "work practice" standard is not a performance standard within the meaning of the Act. Second, HRG-OCAW has always heretofore in these proceedings framed the issue in terms of a specific, zero-exposure requirement, a requirement which it called a performance standard. And, third, even in the abstract the Act specifically gives OSHA authority to adopt regulations based upon requirements other than a performance standard. (Section 6(b)(5).)

1. *The Present Standards Are "Expressed In Terms of Objective Criteria And of the Performance Desired", Within the Meaning of the Act.*

The Act simply says "[w]henever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired". (Section 6(b)(5).) HRG-OCAW would transmute this sentence into a strict command to issue one particular

kind of "performance" standard, *i.e.*, a regulation stated in terms of a numerical limit on the quantity of a given substance in the air, or in a liquid or solid mixture.

The Act is not nearly so restrictive. Here, the standard is in fact "expressed in terms of objective criteria". For example, the objective criteria in the regulations for EI include requirements for closed vessels for chemical reactors, negative-pressure (vacuum) systems for transfer of materials, air scrubbers, glove boxes, closed sampling ports, restricted areas, protective clothing and respirators, and decontamination measures. The standard applies to EI manufacture, processing, repackaging, release, handling or storage, except respecting solid or liquid mixtures of less than 1% EI.

Moreover, there is nothing in the Act to indicate that these are not also requirements which express the "performance desired".

The legislative history of the Act contains a few valuable clues as to what Congress intended in directing OSHA "whenever practicable" to express its standard in terms of "objective criteria" and of the "performance desired". In the 91st Congress, the initial bills to enact a health and safety law in both the House and Senate were split between those calling for standard-setting by the Secretary of Labor [10] and those relying upon an Occupational Safety and Health Board.[11] The debate in both the House and Senate focussed upon the

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[10] *E.g.*, H. R. 843, 91st Cong., 1st Sess. (1969); H. R. 3809, 91st Cong., 1st Sess. (1969); H. R. 4294, 91st Cong., 1st Sess. (1969); S. 2193, 91st Cong., 1st Sess. (1969).

[11] H. R. 13373, 91st Cong., 1st Sess. (1969); S. 4404, 91st Cong., 1st Sess. (1969).

propriety of reposing both the standard-setting authority and the enforcement authority in the Secretary of Labor.

None of the early bills contained provisions equivalent to the Act's present direction to state standards in terms of "objective criteria" and "performance desired". The provision first appeared in the bill reported out of the House Committee on Education and Labor. See H. R. Rep. No. 91-1291, 91st Cong., 2d Sess. at 4 (section 7(a)(4)), 18-19 (1970). However, the provision was omitted from the floor substitute for the Committee bill, which substitute passed the House on November 24, 1970. 116 Cong. Rec. 38,723-38,733 (daily ed., November 24, 1970). The House-passed bill called for standards to be set by an independent Board and not by the Secretary of Labor. The bill reported by the Senate Committee on Labor and Public Welfare also had been revised to include the provision requiring specification of "objective criteria" and "performance desired". S. Rep. 91-1282, 91st Cong., 2d Sess. at 7, 29 (1970). The Senate Committee bill called for standards to be set by the Secretary of Labor; the Committee bill passed the Senate without appreciable change. 116 Cong. Rec. 37,632 (daily ed., November 17, 1970). The Conference Committee resolved the differences between the Senate- and House-passed versions in favor of standards set by the Secretary of Labor, but along with the provision under discussion requiring the Secretary to express the standards in objective, definite form. H. R. Rep. No. 91-1765, 91st Cong., 2d Sess. at 4-6, 33-36 (1970) (Conference Report).

Thus, the requirement for objectively-stated and definite standards stemmed from a compromise with provisions giving the Secretary of Labor standard-set-

ting authority.[12] The provision in referring to "objective criteria" and "performance desired" does not call only for regulations to be stated in terms of numerical limits as HRG-OCAW would have it. Rather, the focus is on specificity and objectivity so that persons governed by the standard will know what is expected of them and similarly that enforcement by the Secretary (the standard-setter) can proceed more even-handedly. Given the circumstances, it is no surprise that OSHA considers these very explicit and definite standards to be performance standards within the meaning of paragraph 6(b)(5) of the Act.[13]

OSHA's standards might indeed be objectionable, but not on the ground that they somehow are not "objective" or do not state the "performance desired".

2. *HRG-OCAW Has Heretofore Always Framed the "Performance" Standard Issue In Terms of A "Zero Exposure"*

Throughout the proceedings before OSHA and before the Third Circuit, HRG-OCAW did not contend that a performance standard as a generic matter was superior to or more appropriate than a work-practice standard

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[12] This is the same compromise that produced the substantial-evidence criterion for judicial review of OSHA's rulemaking orders, which criterion was the subject of the Petition in No. 74-789. See the discussion of the judicial-review aspects of the compromise *supra*, at 9; see also *Associated Industries of New York State* v. *Department of Labor*, 487 F.2d 342, 348-349 (2d Cir. 1973) (opinion by Friendly, J.).

[13] See Occupational Safety and Health Administration, *Draft Environmental Impact Statement On Proposed Regulation: Handling Of Certain Carcinogens*, at 20 ("The ETS [emergency temporary standard] is a performance standard . . . .") (May 3, 1970).

or other requirement. Rather, HRG-OCAW always argued for a zero-tolerance standard, which is a performance standard, albeit an extreme one. Initially, in early 1972 when HRG-OCAW filed with OSHA its petition for an emergency standard it framed its single proposed standard applicable across-the-board to each of ten chemicals in terms of a zero-exposure standard, not in terms of a general performance standard. (Pet. Appx. at 20a.) And, thereafter, in the proceedings leading to adoption of the permanent standard, HRG-OCAW supported instructions to the advisory committee that it consider only one standard for all fourteen chemicals (see *supra,* at 7; Pet. Appx. at 20a-22a), and argued that the one standard should be a zero-exposure standard.

Then in the Third Circuit, HRG-OCAW similarly objected to "the Secretary's erroneous failure to order a performance standard allowing no detectable level of exposure" (Court of Appeals Brief for HRG-OCAW Petitioners, at 21). They also explicitly stated to the Third Circuit that

> "The standard [HRG-OCAW] sought is not a guarantee that no exposure will ever result. It is, however, a performance objective whose purpose is to eliminate all measurable exposure which results from the design and forseeable operation of a process." (*Id.* at 30.)

And, further, HRG-OCAW told the Third Circuit:

> "Perhaps the greatest irony respecting respondent's [OSHA's] refusal to adopt a no measurable exposure performance standard is that his final standards did include a type of performance standard in the exemptions from regulation for certain mixtures containing these carcinogens—precisely

> the action which he concluded the record would not support. Thus, the Secretary concluded that for eight of the chemicals, mixtures containing less than one percent of the chemical would be exempt from regulation and for the other six the exemption is set at 0.1%." (*Id.* at 31.)

Given this background of OCAW-HRG's petitions to OSHA, positions expressed in the permanent rulemaking proceeding, and arguments to the Third Circuit, neither OSHA nor the court below should be faulted for considering the HRG-OCAW petitioners' claims in terms of a zero-exposure or no-detectible-level standard.

3. *The Act Explicitly Grants Discretion To OSHA To Adopt A Performance Standard Or To Employ A Substitute*

In pertinent part, paragraph 6(b)(5) of the Act requires OSHA to consider a performance standard, but at the same time grants OSHA discretion to adopt a substitute:

> "*Whenever practicable,* the standard promulgated shall be *expressed in terms of objective criteria* and of *the performance desired.*" (Emphasis added.)

Here, OSHA found that it was not "practicable" to adopt the zero-exposure "performance" standard advocated by HRG-OCAW, because "no possible exposure to the carcinogens under any circumstances could only be guaranteed by a total ban on the manufacture, use (even for cancer research), and transportation of the substances". (Pet. Appx. at 21a.)

On the administrative record, OSHA said "a safe level of human exposure to any of the 14 carcinogens cannot be established by application of present knowl-

edge". (Pet. Appx. at 20a.) Yet, on the other hand, OSHA also said

> "*a conclusion that safe levels do not exist seems questionable* in view of other studies, some in the area of carcinogenicity which demonstrated that below a certain amount of a single or cumulative dosage, no detectible harm is caused, or if harm is caused, the extent of such harm will be of no practicable importance because the latency period prior to manisfestation of harmful effects will be of greater duration than the normal lifespan of man." (*Id.* at 21a (emphasis added).)

In such circumstances, where the precise acceptable levels of exposure were debatable as a scientific matter, OSHA properly could rely on "work practice" requirements to mandate reduction of exposure to the regulated chemicals to appropriate minimal levels:

> "Accordingly, the intent of the standards is to reduce exposure of workers to any of the listed substances to the maximum extent practicable consistent with continued use." (*Id.* at 21a.)

This constitutes one of the circumstances contemplated by Congress where OSHA could properly exercise the discretion given in paragraph 6(b)(5) of the Act to determine a performance standard that was "practicable".

As noted, the Third Circuit understandably did not address the general and rather abstract issue of whether the particular standards OSHA adopted were performance standards or, if they were not, were they "practiable" alternatives, because the issue was not presented to it. In the SOCMA respondents' view the OCAW-HRG petitioners in this Court have framed the performance-standard issue in expansive terms in an effort

to gain yet "another bite at the apple", *i.e.*, OCAW-HRG remains interested in pressing for zero-exposure, but at this juncture they must approach the matter backhandedly by presenting the abstract issue of performance standard versus work practice standard.

4. ***Experience With OSHA's Prior Regulation Of EI As An Air Contaminant Was Not Properly Evaluated By OSHA In The Rulemaking Proceedings, But The HRG-OCAW Petitioners Seek To Draw An Erroneous Conclusion From This Impropriety***

In the Petition, HRG-OCAW point out that shortly after OSHA's creation, OSHA had adopted numerical performance standards for nearly 400 chemicals and substances as air contaminants. (Petition at 11 n.11, 17.) HRG-OCAW criticize the Third Circuit for not requiring OSHA to evaluate the experience under these air contaminant standards in deciding whether or not to rely on performance standards in these regulations. In SOCMA's view, criticism is warranted but not for the reasons HRG-OCAW suggest.

The 400 air contaminant standards had originally been issued under the Walsh-Healey Act, 41 U.S.C. §§ 35-45. The Occupational Safety and Health Act in subsection 6(a) authorized OSHA to "promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard. . . ." Under subsection 6(a), OSHA could promulgate such standards without complying with the procedural requirements of the Administrative Procedure Act or of the Occupational Safety and Health Act itself. This special authority was limited in time to a period extending for two years from enactment. OSHA had deemed the Walsh-Healey Act standards to

be "national consensus standards" and had adopted them as its own standards under subsection 6(a). They were (and are) codified as 29 C.F.R. § 1910.93, Tables G-1, G-2 & G-3 (1974).

The air contaminant standards included standards for a couple of the fourteen chemicals. Importantly, such a standard was in existence for EI. Somewhat curiously, the EI air contaminant standard is still effective. Under 29 C.F.R. § 1910.93, Table G-1, an employee's exposure to ethyleneimine is limited to an eight-hour time weighted average of 0.5 ppm (parts per million) and 1 mg/M ^{3} (milligram per cubic meter) of EI in air in any eight-hour work shift of a forty-hour work week.

SOCMA agrees with OCAW-HRG that in adopting its new regulation for EI, OSHA had to consider "experience gained under this and other health and safety laws . . ." (§ 6(b)(5)), including particularly experience under the EI air contaminant standard. Indeed, paragraph 6(b)(8) of the Act goes even further and explicitly requires OSHA to include in its *Federal Register* publication of a rulemaking order a statement of reasons why the new standard should be adopted to replace the national consensus standard:

> "Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, *the Secretary shall,* at the same time, *publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard.*" (§ 6(b)(8) (emphasis added).)

OSHA did not even colorably comply with the requirement of paragraph 6(b)(8).[14]

But the point to be drawn from OSHA's derelictions is not that a numerical standard rather than a work-practice standard had to be adopted for EI, and also for the other 13 chemicals. The air contaminant standard for EI stood alone. It was not backed up by other control measures, such as protective clothing and personal equipment requirements, mandatory specification of regulated areas, required labels and warning signs, special decontamination steps, required reports, and medical surveillance. What OSHA has done in the standards for the fourteen chemicals including EI is to rely in large part on work practice requirements, but to build in a large number of redundant or back-up control measures, all of which taken together operate, as OSHA said, "to reduce exposure of workers . . . to the maximum extent practicable consistent with continued use." (Pet. Appx. at 21a.)

In contrast to HRG-OCAW, in SOCMA's view OSHA should have looked carefully at the experience under the air contaminant standard for the purpose of evaluating whether a further and new regulation of EI was needed at all. That inquiry is what paragraph 6(b)(8) intends and indeed requires. To SOCMA's knowledge there have been no adverse em-

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[14] SOCMA raised the issue of this default in briefs to the Third Circuit (Court of Appeals Brief for SOCMA Petitioners on EI, at 24, 51-52), but that court did not see fit to address the question.

ployee health effects due to EI; the air contaminant standard has provided adequate regulation.[15]

In large part, OSHA never focussed on its experience with the air contaminant standards for EI because HRG-OCAW insisted on one single standard for all of the fourteen chemicals despite the obvious differences in physical properties, chemical characteristics, and toxic, carcinogenic or other health effects. HRG-OCAW should not now be heard to complain of a failure by OSHA to look at experience with prior regulations for EI, and especially it should not use that failure as a prop for a general argument in support of a "performance standard".

C. The Act Does Not Require OSHA To Promulgate Monitoring Requirements At This Particular Time When Such Requirements Have Not Yet Been Developed Or Identified

OSHA specifically noted in its rulemaking order that it had not incorporated in each or any of the standards "provisions for specific techniques or instruments for environmental monitoring". (Pet. Appx. at 28a.) It had, however, asked the National Institute for Occupational Safety & Health ("NIOSH") to develop such provisions "on a priority basis". (*Id.*) HRG-OCAW complain that the Third Circuit improperly sanctioned such an arrangement for deferred promulgation of monitoring provisions. HRG-OCAW assert that para-

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[15] EI is a strong blistering agent and must be handled with great care. The SOCMA respondents remain of the view that it is not a carcinogen, nor does it meet OSHA's criterion for denomination as a substance with carcinogenic "potential". Because the Third Circuit adopted such a limited standard of review that it could not consider whether EI in fact meets OSHA's own criterion, SOCMA has submitted concurrently with this Brief a Petition for Rehearing of Order Denying Certiorari in No. 74-789.

graph 6(b)(7) of the Act requires promulgation of monitoring provisions contemporaneously with the other portions of the standards.

In pertinent part, paragraph 6(b)(7) says: "*Where appropriate,* . . . such standard shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." (Emphasis added.)

The Third Circuit got to the heart of the matter when it said simply that OSHA had "deferred implementation of monitoring requirements pending further scientific development of methods for doing so". (Pet. Appx. at 12a.) The court said it would not disturb such a "pragmatic" decision by OSHA.

The SOCMA respondents agree with the Third Circuit on this issue. Where no monitoring measures had yet been developed or identified,[16] it could not be "appropriate" under paragraph 6(b)(7) to provide for such measures in the standards.[17]

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[16] In addition, OCAW-HRG certainly have not identified any such monitoring techniques for any of the fourteen chemicals.

[17] In Occupational Safety and Health Administration, *Supplement To Final Environmental Impact Statement On Proposed Regulation: Handling Of Certain Carcinogens,* the Agency stated:

> "No opposition to the concept of monitoring has been expressed during the consideration of the proposed standards; the major problems raised relate to the degree of sensitivity to be required, and the present unavailability of reliable monitors.
>
> "The Director of the Division of Laboratories, National Institute for Occupational Safety and Health, estimates that it will take approximately two years to develop methods for all 14 carcinogens which will be suitable for general use at the ppb (parts per billion) level . . . ." (*Id.* at 65.)

Again, much of the present trouble stems from HRG-OCAW's insistence on one standard to cover all fourteen chemicals. Because of the diversity of the chemicals, no one monitoring method or group of methods was satisfactory. As the Third Circuit noted, the entire rulemaking proceeding was adversely affected by OSHA's adoption of HRG-OCAW's one-standard-for-all approach right up to the time the final standard was issued:

> "[T]he value of notice and comment from interested parties in a hearing for rulemaking was not realized in this case. As an example, the advisory committee was instructed that only one set of standards would be promulgated for all fourteen chemicals, despite the substantial differences in their properties and their industrial and laboratory uses. After the public hearings had been concluded, however, the Secretary issued separate standards for each chemical. Had the proposed rule recited the separate standards, the presentation of pertinent objections, comments and data would have made the public hearings far more valuable to all concerned." (Pet. Appx. at 8a (footnotes omitted).)

Then too, monitoring requirements in a work practice standard provide a back-up or redundant protection. The immediate presence of every single safeguard or back-up system of protection is not essential or necessary to the successful implementation of the standards. OCAW-HRG imply that stringent enforcement of standards is extremely difficult without the monitoring requirement. (Petition at 22.) This contention is factually incorrect in these circumstances. The work practice requirements are all visually observable. Inspectors have had and will have no dif-

ficulty in determining compliance with requirements for closed vessels for chemical reactions, negative-pressure (vacuum) systems for transfer of materials, air scrubbers, glove boxes, closed sampling ports, restricted areas, protective clothing and decontamination measures.

CONCLUSION

In the view of the SOCMA respondents, OSHA's proceedings were faulty, and the Third Circuit failed to follow the requirements of Section 6 of the Act in reviewing the proceedings. Thus, the SOCMA respondents have a small measure of agreement with the HRG-OCAW petitioners, even though the SOCMA respondents certainly disagree with the HRG-OCAW petitioners respecting which aspects of the administrative proceedings and of the court's review were faulty.

The standards which are the subject of this case are the forerunners for numerous such standards to be developed in the future. It is consequently quite important to OSHA and to those affected by its regulations and standards that the judiciary through discerning review provide a satisfactory assessment of those standards.

Unfortunately, the bifurcated Third Circuit proceedings have led to piecemeal presentation of important issues to this Court. Now, however, the Court has an opportunity to examine the three legal issues arising from the totality of the Third Circuit's proceedings. In the view of the SOCMA respondents, the two questions posed by this Petition are worthy of this Court's attention, *if* the Court combines them with the single question respecting scope of review presented by the Petition in No. 74-789. To enable the Court to

consider the scope of review issue in No. 74-789 with the questions presented here, the SOCMA respondents submit concurrently a Petition for Rehearing of the Order Denying Certiorari in No. 74-789. Each of the three questions posed raises a legal issue which does not require an extensive examination of the technical matters raised in the court below. In addition, each of the three questions concerns the legislative compromise made by Congress when it conferred standard-setting authority on the Secretary of Labor but hedged that authority with procedural and substantive safeguards. Thus, the questions logically belong together and should be considered by this Court with each other.

Certiorari should be denied if the Court does not wish to consider the questions posed here with the one issue presented in No. 74-789.

Respectfully submitted,

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APPENDIX

APPENDIX A

Statutes Involved

Occupational Safety and Health Act. Section 6 of the Occupational Safety and Health Act (29 U.S.C. § 655 (1970)) provides as follows:

> (a) Without regard to chapter 5 of title 5, United States Code, or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this Act and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.
>
> (b) The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:
>
> (1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health, Education, and Welfare, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendations of an advisory com-

mittee appointed under section 7 of this Act. The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health, Education, and Welfare, together with all pertinent factual information developed by the Secretary or the Secretary of Health, Education, and Welfare, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefor and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a

hearing requested, and specifying a time and place for such hearing.

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Secretary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall

be expressed in terms of objective criteria and of the performance desired.

(6)(A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes that (i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date, (ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and (iii) he has an effective program for coming into compliance with the standard as quickly as practicable. Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: *Provided*, That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more than twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of an order may remain in effect for longer than 180 days.

(B) An application for a temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from the which employer seeks a variance,

(ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefor,

(iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard,

(iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and

(v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means.

A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health, Education, and

Welfare certifies, that such variance is necessary to permit an employer to participate in an experiment approved by him or the Secretary of Health, Education, and Welfare designed to demonstrate or validate new and improved techniques to safeguard the health or safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of title 5,

United States Code, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

(c)(1) The Secretary shall provide, without regard to the requirements of chapter 5, title 5, United States Code, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with section 6(b) of this Act, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency

standard as provided in paragraph (2) of this subsection.

(d) Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

(e) Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this Act, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

(f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is pro-

mulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

(g) In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health, Education, and Welfare regarding the need for mandatory standards in determining the priority for establishing such standards.